OIPE
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. Serial No.: 10/679,166 Group Art Unit: 3733

Filing Date: 10/03/2003 Examiner: Woodhall, Nicholas

Applicants: David C. Szakelyhidi, Jr., et al. Attorney Docket No.: 34548.208

Title: **MAGNETIC TARGETING DEVICE**

COMBINED RULE 131/132 DECLARATION OF CO-INVENTORS DAVID C. SZAKELYHIDI, JR., ALEX V. CARDINALI, JOEL D. STITZEL, ALFRED A. DURHAM, AND ALFRED L. WICKS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

To the Commissioner:

We, David C. Szakelyhidi, Jr., Alex V. Cardinali, Joel D. Stitzel, Alfred A. Durham, and Alfred L. Wicks, individually and collectively, do hereby declare as follows:

1. We are each co-inventors of Claims 1-66 of the above-identified patent application (as originally filed and subsequently amended) and co-inventors of the subject matter described and claimed therein. As such, we are, individually and collectively, intimately familiar with the above-identified patent application and the subject matter claimed therein.

2. We are each intimately familiar with the contents of U.S. Patent Application Publication US 2005/0080427, to Govari et al. The Govari et al. application was published on April 14, 2005, and claims priority to U.S. patent application Serial No. 10/198,514, filed on July 18, 2002. Thus, the earliest effective filing date of the Govari et al. published patent application is July 18, 2002.

3. The above-identified application for patent claims priority to provisional patent application Serial No. 60/415,952, filed October 3, 2002, a true and complete copy of which is attached hereto as Exhibit A and incorporated herein. The filing date of the provisional application (October 3, 2002) is less than one year after the earliest effective filing date of the Govari et al. published patent application (July 18, 2002).

4. All of the work described in this declaration was performed personally by one or more of us (David C. Szakelyhidi, Jr., Alex V. Cardinali, Joel D. Stitzel, Alfred A. Durham, and/or Alfred L. Wicks) or at our direction and under our direct supervision. All of the work described in this declaration was performed in the United States of America. All of the work described in this declaration was performed, and the corresponding data generated, prior to July 18, 2002. The work described in the following paragraphs shows that we reduced to practice the invention recited in the now-pending claims of this application prior to July 18, 2002.

5. Prior to July 18, 2002, having earlier jointly conceived the idea of a targeting device for detecting screw holes within an intramedullary nail, we jointly began work on reducing the idea to practice. Ultimately we reduced to practice a device that included a magnet configured to be positioned within a longitudinal opening in an intramedullary nail. The magnet was configured to provide a directional field that could be tracked in three dimensions (*i.e.*, in the *x*, *y*, and *z* planes). The device further included a positioning device to detected the location of the magnet within the intramedullary nail. In due course, we perfected the device and submitted an Intellectual Property Disclosure report to Virginia Tech University. Attached hereto as Exhibit B is a true and complete copy of the Invention Disclosure Report that we, David C. Szakelyhidi, Jr., Alex V. Cardinali, and Joel D. Stitzel, submitted to Virginia Tech Intellectual Properties, Inc. (the tech transfer arm of Virginia Tech University) on behalf of all of the co-inventors. Exhibit B is incorporated herein.

(a) I, David C. Szakelyhidi, Jr., personally completed the Invention Disclosure Report attached hereto as Exhibit B and declare Exhibit B to be a true and complete copy of the same.

(b) Pages 4, 7, 8, 9, 10, and 11 of Exhibit B have been redacted to remove the dates present within the original document. All of the dates redacted from pages 4, 7, 8, 9, 10, and 11 of Exhibit B are on or earlier than July 18, 2002.

(c) At the bottom of page 3 of Exhibit B, I, David C. Szakelyhidi, Jr., described the invention as follows: "This is a new prototype device. It is meant to enhance and/or replace existing technology used to target and drill distal intramedullary nail (IMN) screw holes."

(d) At page 4 of Exhibit B, under section 3, is a brief time line of the conception and initial reduction to practice of the invention described in Exhibit B. The dates redacted from page 4 of Exhibit B are all prior to July 18, 2002.

(6) At page 4 of Exhibit B, under section 4, is a brief description of the advantages of the presently claimed invention. This section of Exhibit B reads as follows:

> The device functions as a precision magnetic targeter which provides visual feedback of alignment. It uses a permanent magnet and magnetic sensors which can be used to align a drill bit so that it is parallel to the axis of the hole for drilling IMN interlocking screw holes. The novel features of this device include the following:
>
> - No active or passive electronics in vivo.
> - No x-ray imaging needed for targeting
> - Single target magnet with unique axisymmetric field
> - Real time feedback of alingment
> - Adjustable sensitivity
> - Visual, audible, or tactile positioning feedback is possible
> - Novel magnet orientation
>
> (See Attachment D for a more detailed description of the prototype device.)

(7) "Attachment D" referenced in the above-quoted passage is a highly detailed, 19-page attachment that is included as an integral part of Exhibit B. "Attachment E" of Exhibit B is the last page of Exhibit B. "Attachment E" is a brief summary of how the work leading to the reduction to practice of the present invention was funded. All of the dates redacted from

"Attachment E" are prior to July 18, 2002.

8. "Attachment D" of Exhibit B includes a highly detailed description of the exact invention that is now claimed in the present patent application. In particular, note that Figure 4 of Attachment D (at page 7) is the same as Fig. 1 of the provisional application attached hereto as Exhibit A, and is substantially identical to Fig. 1 of the present non-provisional patent application. Likewise, Figure 5 of Attachment D (at page 9) is the same as Figs. 3a and 3b of both the provisional application attached hereto as Exhibit A, and Figs. 3a and 3b present non-provisional patent application. (Note that Figs 3a and 3b of the non-provisional application are stylized drawings, rather than photographs presented in Exhibit B and in the corresponding provisional application.) Also Figure 8 of Attachment D (at page 12) is identical to Fig. 2 of the provisional application attached hereto as Exhibit A, and substantially identical to Fig. 2 of the present non-provisional patent application.

9. The same exact device as described in Exhibit B is disclosed and claimed in the above-referenced non-provisional patent application and the provisional application attached hereto as Exhibit A.

10. We, David C. Szakelyhidi, Jr., Alex V. Cardinali, Joel D. Stitzel, Alfred A. Durham, and Alfred L. Wicks, individually and collectively, hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Combined Rule 131/132 Declaration is directed.

Date: 3/14/08

David C. Szakelyhidi, Jr., Co-inventor

Date: ______

Alex V. Cardinali, Co-inventor

Date: ______

Joel D. Stitzel, Co-inventor

Date: ______

Alfred A. Durham, Co-inventor

Date: ______

Alfred L. Wicks, Co-inventor

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Date: ________

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David C. Szakelyhidi, Jr., Co-inventor

Date: 03/17/2008

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Alex V. Cardinali, Co-inventor

Date: ________

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Joel D. Stitzel, Co-inventor

Date: ________

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Alfred A. Durham, Co-inventor

Date: ________

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Alex V. Cardinali, Co-inventor

Date: 3/16/2008

Joel D Stitzel
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Joel D. Stitzel, Co-inventor

Date: __________

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Alfred A. Durham, Co-inventor

Date: __________

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PATENT & TRADEMARK OFFICE

Date: __________

David C. Szakelyhidi, Jr., Co-inventor

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Joel D. Stitzel, Co-inventor

Date: 3/10/08

Alfred A Durham

Alfred A. Durham, Co-inventor

Date: __________

Alfred L. Wicks, Co-inventor

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Date: ____________

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Date: ____________

Joel D. Stitzel, Co-inventor

Date: ____________

Alfred A. Durham, Co-inventor

Date: 3/15/08

Alfred L. Wicks, Co-inventor

docketed.

UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/415,952	10/03/2002		80	34548.208	5		

CONFIRMATION NO. 3117

DEWITT ROSS & STEVENS, S.C.
Intellectual Property Dept.
Suite 401
8000 Excelsior Drive
Madison, WI 53717-1914

FILING RECEIPT

OC000000008977944

Date Mailed: 10/21/2002

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

David C. Szakelyhidi JR., Blacksburg, VA;

If Required, Foreign Filing License Granted 10/18/2002

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Magnetic targeting device applied to distal interlocking of intramedullary nails

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LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

PENGAD 800-631-6989
EXHIBIT
A

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(b)(2).

ATTORNEY DOCKET NO: 34548.208

INVENTOR(S):

Last Name	First Name	Middle Initial	Residence (CITY and EITHER STATE OR FOREIGN COUNTRY)
Szakelyhidi, Jr.	David	C.	Blacksburg, Virginia

TITLE OF THE INVENTION (280 characters max)

MAGNETIC TARGETING DEVICE APPLIED TO DISTAL INTERLOCKING OF INTRAMEDULLARY NAILS

PLEASE SEND ALL CORRESPONDENCE TO:

Intellectual Property Dept.
DEWITT ROSS & STEVENS, S.C.
8000 Excelsior Drive, Suite 401
Madison, WI 53717-1914
USA

ENCLOSED ARE THE FOLLOWING DOCUMENTS:

[X] Specification consisting of 269 pages, including attachments

[X] Drawings consisting of 5 sheets

[X] A check for $80 to cover the provisional filing fee (applicant claims small entity status)

[X] The Commissioner is hereby authorized to charge any fees or credit any overpayments to Deposit Account Number 18-2055.

[ ] Other (specify)________________________________

EL901770305US

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No

[ ] Yes, the name of the U.S. Government agency and the Government contract number are:__________

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Post Office to Addressee, in an envelope addressed to:

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Express Mail Label No: EL901770305US
Date of Deposit: October 3, 2002
Signature: Marilyn L. Josenly

MAGNETIC TARGETING DEVICE APPLIED TO DISTAL INTERLOCKING OF INTRAMEDULLARY NAILS

Inventor:

David C. Szakelyhidi Jr.

REFERENCE TO CITATIONS

Complete bibliographical citations to the references can be found in the list preceding the Claims.

FIELD OF THE INVENTION

The present invention relates to a method and device for positioning locking screws for intramedullary nails. The invention describes sensitive methods for magnetic detection of transverse interlocking screw holes in real time.

DESCRIPTION OF THE PRIOR ART

Each year, approximately 14,000 femoral and 12,000 tibial internal fracture repairs are performed by orthopedic surgeons in the United States. Internal fixation of long bones has allowed shorter hospitalization times and earlier weight bearing for the patient, compared to plaster cast or external fixation.

The medical procedure involves the fixation of long-bone fractures by inserting an intramedullary nail (IMN), a long, thin-walled, metallic nail, into the medullary canal of the damaged bone. The surgeon introduces the implant by creating an opening in the proximal end of the bone that opens into the canal. The bone fragments are aligned, and the IMN is passed through the fragments, creating a means for internal support.

The IMN is prefabricated with holes in the proximal and distal ends, which are designed to accept transverse interlocking screws. These screws are essential to control the rotation and translation of the bone fragments with respect to each other. To insert these transverse, interlocking screws, it is necessary to align and drill through the bone to meet the proximal and distal interlocking screw holes of the IMN.

Since their introduction, all facets of the IMN have evolved, from the shape and materials to the methods and procedures used to implant them. While some procedures are universally accepted by orthopedic surgeons, there is sharp disagreement regarding many others. Controversies arise especially when discussing methods of interlocking screw insertion. In response, there is a great deal of work being done to improve methods for targeting, drilling and inserting the distal interlocking screws.

One of the most difficult parts of intramedullary nailing of long bones is locating and drilling the interlocking screw holes. IMN interlocking screw placement requires the surgeon to locate the openings in the nail, center the drill and advance the bit through the bone to meet them. The interlocking screws are then inserted. Proximal interlocking screw placement is relatively easy because the openings can be located with an external guide attached to the end of the IMN. However, this technique does not work well for distal interlocking screw placement.

Complicating the process of identifying and drilling the distal interlocking screw holes is the deformation that routinely occurs to the IMN upon implantation in the medullary canal. Studies have shown that deformation occurs in several planes due to medial-lateral and anterior-posterior flexion of the distal nail after it has been inserted (*Krettek et al.*, 1996; 1997; 1998). On insertion, the distal IMN may exhibit a mean lateral deflection of 4.5. 3.0 mm and dorsal deflection of 7.8. 5.8 mm. In addition, rotational deformation of the distal IMN has been measured at 0.3 . 0.7 degrees. The distal nail may deform from its original shape in any of these coordinates to some degree. The deformation of the nail is due to the shape of the medullary canal where the nail is inserted. The medullary canal shape varies widely from person to person, and it is not possible to predict how the nail will deform accordingly. Therefore, it is difficult to determine what the resultant location of the distal interlocking holes will be relative to their initial position.

In addition, there are narrow tolerances between the screw and interlocking opening. To avoid any complications, it is obviously important to place the interlocking screws accurately. These tolerances must be taken into account when targeting and drilling, so as to allow room for proper screw insertion. If the drill bit is not within the tolerance constraints or misses the hole, a second attempt must be made. Unfortunately, once a hole is started, it is difficult to correct. In some cases, the bone may be too weak to accommodate another hole, and then bone grafting or other means of fracture fixation must be employed.

One method that is capable of providing precise location of the transverse distal holes in IMN's (also known as locking rods) uses X-rays. Correct alignment is indicated when the desired interlocking hole appears as a perfect circle under X-ray fluoroscopy, with the drill bit in the exact center. If alignment is lost, the drilling must be stopped and the drill bit realigned using further X-ray imaging. In its most rudimentary form, the opening is drilled with freehand means. The process of drill bit centering requires the soft tissue of the patient's extremity to be separated all the way to the bone so the surgeon has sufficient room to maneuver. X-ray imaging requires long periods of X-ray exposure first, to identify the location of the transverse distal hole and second, to correctly drill the hole. Thus, X-ray exposure may accumulate to dangerous levels for both the surgeon and patient. In addition, X-ray imaging necessitates moving X-ray equipment into and out of position, allowing numerous opportunities for loss of alignment each time the equipment is moved.

The need to reduce damage to soft tissue during these procedures has led to the use of less invasive techniques. These techniques include percutaneous methods wherein surgical instruments are inserted through small incisions in the skin, thus reducing soft tissue damage. Methods to optimize percutaneous techniques include aiming devices, which rely on mechanical approaches to locate the distal screw holes. The simplest of these mechanical devices uses an external arm with openings that correspond to the screw opening location in the IMN. Once the IMN is implanted, the external guide arm is attached firmly to its proximal end creating a solid link. The openings corresponding to the screw openings then serve as a drill sleeve for drill alignment. Unfortunately, due to the tight tolerances required for screw location and the degree of distal nail deformation occurring, this approach still requires an inordinate amount of X-ray exposure and still carries the risk of misplacing the opening. Further, while methods to limit exposure of individual patients to X-rays have been explored, the need to perform the surgery using X-rays for detection means that the surgical team is serially subjected to X-ray exposure.

The desire to target accurately without X-ray imaging has led to recent attempts to use magnets for targeting of the distal IMN screw openings. Devices have been developed that use external magnetic sensors to find the position of a flux field induced in the IMN by permanent magnets or electromagnets (*Brudermann, 1986*). Some devices have even tried to magnetize the whole IMN and look for variations in the magnetic flux that occur around the interlocking holes (*Zacheja et al., 2000*). Other devices target on a magnet placed inside the IMN at the same position as the opening. For instance, U.S. Patent Nos. 5,049,151, 5,514,145 and 5,703,375 to *Durham et al.* teach the use of a pivotable magnetic positioning device to position a guide wire by which a cannulated drill is directed to align the drill bit with the interlocking screw opening. In these inventions, the targeting device is a second, pivoting, magnet, attached to a drill sleeve acting as a compass to direct the drill bit toward the target magnet.

Magnetic targeting has some significant advantages. Magnetic fields can penetrate the IMN and human tissue without being distorted or causing physiologic damage, unlike X-rays. Also, magnetic devices require little power, although some designs incorporate the use of computers to output positioning data. One notable drawback is that the majority of these targeting devices is manufactured to work only with specific nails and is not adaptable to others. In addition, the magnetic field must be powerful enough to be detectable at distances of 10 cm. This is the average maximum distance encountered between the center of the IMN and the exterior of the patient's limb at the thickest site of IMN implantation, usually the femur. While electro-magnets can generate stronger fields, devices that use electric current inside the body to create magnetic fields require stringent FDA approval because of their inherent danger.

U.S. Patent No. 4,621,628 to *Brudermann* describes a method for the magnetic identification of transverse locking holes wherein the sensor is inserted into the IMN and the magnet is placed percutaneously on the broken limb. In this disclosure the sensors, in the form of intersecting Hall elements, are inserted into the IMN to the area of the transverse screw hole and are connected to an external display. The magnet is placed on the surface of the skin until the axis of the field is aligned, wherein a zero point indication is signaled on the display. While *Brudermann* teaches a non X-ray means of detecting the transverse screw hole, it suffers from the draw backs of inserting an electrical device inside the medullary cavity, the low sensitivity of the Hall Effect sensors used to detect the magnets, the lack of three-dimensional resolution to the display and the lack of portability to the entire device.

In a more recent use of magnetic targeting, U.S. Patent No. 6,162,228, to *Durham* describes a method of using a target magnet inserted into the IMN and a target sensor, which is essentially mechanical, having a compass that indicates the position of the target magnet in the IMN. This invention is similar to the other *Durham* patents identified above with the exception that the target magnet produces an output comprising a light or buzzer when the targeting unit is aligned. While this device solves the problem of excessive exposure to X-rays, it has neither the sensitivity to penetrate the combined tissue layers nor the ability to discriminate the orientation of the screw hole in three-dimensional space.

Due to the aforementioned problems with locating the distal screw holes of intramedullary nails, including, excessive X-ray exposure, excessive soft tissue damage, the need for expensive and bulky equipment and the lack of real time imaging, there is a need for a sensitive and easily visualized sensing device that is both portable and safe for use in locating distal transverse screw holes in intramedullary nails.

SUMMARY OF THE INVENTION

The present invention provides a method and device for percutaneously locating proximal transverse screw holes in intramedullary nails using a magnetic target and a sensitive and accurate targeting device.

Specifically, the invention is directed to a device for detecting the location and position of interlocking transverse screw holes within an intramedullary nail for the internal fixation of long bones, the intramedullary nail having a longitudinal opening and transverse locking screw openings. The device includes a magnet adapted to be positioned within the longitudinal opening of the IMN for providing a directional field, wherein the magnet includes a three-dimensional orientation; and a positioning device. The positioning device includes sensing means for identifying the magnet location along the three-dimensional orientation of the magnet, and a drill sleeve.

The present invention is also directed to a method for positioning a locking screw at a desired concealed location within an external surface location. The method comprises positioning a magnet within the concealed location, wherein the magnet includes a three-dimensional orientation; providing a positioning device external to the concealed location, wherein the positioning device comprises sensing means for identifying the magnet location along the three-dimensional orientation of the magnet, and a drill sleeve comprising an axis intended for positioning at the concealed location; and moving the positioning device along the external surface location until the sensing means senses the three-dimensional orientation of the magnet, wherein the axis of the drill sleeve is positioned at the concealed location.

The present invention also provides a target magnet that can be inserted, on the end of a wand, in the cavity of an intramedullary nail to a discrete position proximal to the transverse interlocking screw hole. The magnet has an axisymmetric flux field thereby relating information on its orientation in relation to the screw hole. In addition, the method is designed such that the flux field is detectable at 10 cm, the average maximum distance encountered between the intramedullary canal and the outside of the patient's limb.

The invention further describes a method for sensing the flux field whereby commercially available magnetoresistive (MR) elements are arranged in an elliptical pattern thereby being aligned perpendicular to the lines of flux. The targeting device comprises a sensor comprised of eight MR elements arrayed in an elliptical pattern with the elements comprising four pairs opposing member elements. Because direct centering of the target between members of a pair of MR sensors elicits the same magnitude response from each member of the pair, the difference in output between pair members is relative to the spatial difference of each pair member from the target magnet. By comparing voltage offset between opposing sensors in the array, it can be determined which direction in the field the sensors must be moved to elicit an equivalent output, thus indicating exact centering over the target magnet.

The invention also comprises an easily readable LED display by which the location of the array, in relation to the target magnet, is displayed. The display resembles a "bull's-eye" of eight red LED's, representing the eight MR elements, surrounding a central green LED, representing the target magnet. An illuminated red LED means the target sensor must be moved toward the red light. Moreover, the LED's have a variable brightness that deceases as the target sensor moves toward correct alignment. When all members of the sensor pair are aligned, the red lights will be off and the green light will be illuminated.

In a further embodiment of the invention, the sensor display comprises a handle with the display in the middle and a drill sleeve in the distal end. By this means, the sensor can be aligned with the target magnet and the interlocking drill hole drilled while simultaneously, in real time, monitoring the position of the drill bit in relation to the interlocking screw hole.

It is another aspect of the invention that the target magnet is designed to relay information about its position and orientation in relation to the axis of the transverse interlocking screw hole. Thus, the magnet is designed to have a non-circular, axisymmetric flux field allowing the sensor to distinguish rotation about the z-axis, while the peak flux lines perpendicular from the magnet indicate its exact center.

It is another aspect of the invention that the magnets are designed to provide a flux field that is distinguishable to the MR sensors at a distance of 10 cm, the average maximum distance from the IMN to the surface of the patient's limb.

The objects and advantages of the invention will appear more fully from the following detailed description of the preferred embodiment of the invention made in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS AND ATTACHMENTS

FIGURES:

Fig. 1 is a perspective view of the invention illustrating the target magnet inserted in the IMN and attached to a wand with the target sensing device connected to a drill sleeve.

Fig. 2 is a representation of the flux lines produced by the magnet. The elliptical array is shown in which each sensor lies perpendicular to the flux field. This arrangement allows for equivalent voltage outputs from all the sensors when the array is centered in the flux field over the magnet.

Figs. 3a and 3b are graphs illustrating plots of flux density in the y-z and x-z planes above the chosen cylindrical magnet. The peak is centered exactly over the magnet, parallel with the z-axis and is detectable at the required targeting distance of 10 cm.

Fig. 4 shows a schematic diagram of the sensing device with an insert representing the target magnet and flux lines and the elliptical sensing array in three-dimensional space.

Fig. 5 is a perspective view of the target sensing device illustrating the magnetic sensors arranged in an elliptical pattern of opposing pair members.

ATTACHMENTS:

Attachment 1: website article entitled "Distal Interlocking," from *Wheeless' Textbook of Orthopaedics*

(http://www.medmedia.com/oo4/166.htm)

Attachment 2: website article entitled "Femoral Nails," from *Total Solution for Trauma* (http://www.biometmerck.com/english/products/trauma?femoral.htm)

Attachment 3: website article entitled "Proximal Inter-Locking for Synthes Nail," from *Textbook of Orthopaedics*, (http://www.medmedia.com/004/167.htm)

Attachment 4: website article entitled "Synthes IM Femoral Nail Insertion Techniques," from *Textbook of Orthopaedics* (http://www.medmedia.com/004/165.htm

Attachment 5: website article entitled "Case Discussion: Femoral Nail Stuck Inside the Canal." From http://www.orthoweb.be/question/femur_nail.htm.

Attachment 6: two-page article entitled Orthomatrix Magellan I.M System.

Attachment 7: paper entitled "Critique of Distal Intramedullary Nail Screw Hole Targeting Procedures (David C. Szakelyhidi), dated May 2, 2002.

Attachment 8: set of overhead printouts entitled "Critique of Distal Intramedullary Nail Screw Hole Targeting Procedures (David C. Szakelyhidi), dated May 2, 2002.

Attachment 9: article entitled "Femoral Nail Drill Hole Locator using Stationary Magnet and Magnetic Field Sensor Array."

Attachment 10: set of overhead printouts entitled "IMR Positioning Instrumentation – Application of Hall Effect Sensors." (November 17, 2000).

Attachment 11: Philips Data Sheets relating to Magnetic field Sensors.

Attachment 12: Court-Brown, Charles M., 1991, "Chapter 6 Distal Cross-Screw Insertion," *An Atlas of Closed Nailing of the Tibia and Femur,"* pages 84 – 96.

Attachment 13: Alignment indicating circuit using green LED.

Attachment 14: Signal Conditioning Circuit – A.

Attachment 15: Signal Conditioning Circuit – B.

Attachment 16: Alignment indicating circuit using red LED's

Attachment 17: U. S. Patent 4,621,628 to Brudermann

Attachment 18: U. S. Patent 4,625,718 to Olerud et al.

Attachment 19: U. S. Patent 5,611,353 to Dance et al.

Attachment 20: U. S. Patent 5,617,857 to Chader et al.

Attachment 21: U. S. Patent 5,707,375 to Durham et al.

Attachment 22: U. S. Patent 5,891,158 to Manwaring, et al.

Attachment 23: U. S. Patent 5,987,960 to Messner, et. al.

Attachment 24: U. S. Patent 6,162,228 to Durham

Attachment 25: U.S. Patent 6,205,411 to DiGoia, III et al.

Attachment 26: U.S. Patent 6,347,460 to Forrer, et al.

DETAILED DESCRIPTION OF THE INVENTION

As embodied and broadly described herein, the present invention is directed to a method and device that is capable of detecting the location and position of interlocking transverse screw holes within an intramedullary nail (IMN) for the internal fixation of long bones.

Current medicine has identified that the most efficient way to set broken long bones is by placement of an IMN within the medullary cavity of the bone. The broken bone must be fixed to the IMN such that the bone does not move about the nail and is held in place by its fixation to the nail. This requires insertion of a screw through the various broken parts of the bone such that they are in proper alignment with each other and anchored to the intramedullary nail.

While the use of an IMN has been found to be far more efficient in allowing the bone to heal, it may be appreciated that the identification of the screw holes has proven difficult. The present invention provides a method and device that is much more time efficient, less invasive and less dangerous than those previously used.

While the preferred embodiment of this invention will be described with respect to the use of an IMN for repairing long bones, such as femurs, it is within the scope of the present invention to have other uses. These include: tracking and positioning of medical instruments, including endoscopes, catheters and implants within the body; use of location and positioning devices used in industry, particularly with materials that are X-ray sensitive; replacement of jigs and other measurement systems used in industry and manufacturing; providing positioning feedback for robotic devices; and, any process requiring blind hole targeting in non ferrous materials including, precise positioning of opposing elements such as in cabinetry making, fiberglass fabrication and construction and processes involving ceramic and tile fabrication and installation. As previously discussed, the use of electromagnets is not recommended for in-vivo uses; however, electromagnets may be well suited to these other uses of the invention.

Referring now to **FIG. 1**, there is illustrated a hollow intramedullary nail (IMN) **10**, known to the art. The IMN **10** includes transverse locking screw openings **12, 14.** The IMN **10** is placed within the medullary cavity of a long bone **20**, such as a femur. A target magnet **30**, attached to a wand **32** or other like device, is then inserted into the IMN **10** in a specified orientation to a locking point **34** at the most distal screw hole **14**.

The magnet **30** is designed to be axisymmetric with non-circular flux lines. The north pole of the magnet **30** must face medially (along the z-axis **36**) so that it projects a magnetic field having a central line **37** of flux parallel to the axis **39** of the interlocking opening **14**. Designed in this manner, the flux field **50** of the magnet **30** relates information about its three-dimensional orientation along the x-axis **41**, the y-axis **43**, and the z-axis **36**.

A target sensor **40** is then applied percutaneously to the approximate region of the opening **14**. In the embodiment illustrated the sensor includes an array **42** of sensors **44**, described more fully below, on a handle **46**. Located at the distal end of the sensor **40** is a drill sleeve **48**.

The sensor **40** is designed to detect the magnetic flux lines of the target magnet **30** and can be aligned to precisely identify the magnet **30** location. The target sensor **40** is designed to have a sufficient sensitivity and resolution to operate at a range of 10 cm from the magnet **30**. The field strength of the magnet **30** at this distance will be below one Gauss, which is close to the value of the Earth's magnetic field. Therefore, a sensor is needed that can sense very small changes in magnetic field. Sufficient resolution is gained by using a sensor that has a sensitive range of -2 to +2 Gauss. Such components are commercially available. For example, Phillips Electronics currently makes a magnetoresistive (MR) field sensor that requires only 120 milliwatts of power, which is appropriate for battery powered operation (Phillips Semiconductors KMZ10B).

In addition, these sensors can provide sensing feedback for small variations of magnetic fields at a distance of 10 cm from the target magnet. The KMZ10B sensors have a sensitivity of 1.6 millivolts change per Gauss. They can also be nulled so that their outputs only represent changes in the flux lines emitted from the target magnet, thus allowing extraneous fields from other sources in the operating room to be ignored. Further, the KMZ10B sensors are extremely versatile; being very robust, able to withstand extremes in temperature, chemical challenges as well as having a low energy requirement. In addition, these sensors can also be configured in an array so that their collective outputs may be used for targeting.

As illustrated in **FIGS. 1 and 2**, the target sensor **40** includes an array **42** of sensors **44**. Although the number of sensors **44** can vary in number from a minimum of two, in its preferred embodiment the array **42** of sensors includes eight MR sensors **44a-h** in an elliptical array forming four pairs (**44a-e, 44b-f, 44c-g,** and **44d-h**). Each sensor **44** in a pair opposes the other member of the pair. Each MR sensor **44** produces a maximum output when flux lines are perpendicular to its sensitive side. This allows the angle and magnitude of the detected field to be known. As illustrated in **FIG. 2**, the elliptical arrangement of the sensors **44** allows them to be geometrically aligned with flux lines **50** of the target magnet **30**. Each individual sensor **44** is oriented perpendicular to the flux lines **50** that project radially outward from the target magnet **30**, while being centered about the peak flux lines emitted along the z-axis. A plot of the flux lines in the x-y plane is illustrated in **FIGS. 3a and 3b.**

The arrangement of the sensors **44** so described allows each sensor **44** in the array to be excited by the same magnitude and angle of flux when centered about the z-axis **36** of the magnet **30**, and will produce the exact output voltage. The sensor array can move up and down in a plane perpendicular to the z-axis **36** and retain the same feedback of position because the field shape in that plane remains constant. It becomes stronger as the sensors **44** get closer to the target magnet **30**, as best illustrated in **FIG. 2**. Because the sensors **44** are aligned in opposing pair members, centering each pair over the target magnet **30** elicits the same magnitude output from each member of the pair. Upon exact centering, one member will "cancel out" the other member. Any deviation from exact center, in either rotation or translation, will cause an offset in opposing members of the sensor pair. By comparing voltage offset between opposing sensors in the array, the direction in the field can be determined. Reference is made to **FIG. 4**, for a schematic of a preferred embodiment, in which the inset represents the sensory array relative to the flux lines **50** generated by the magnet **30**. As described the sensing device allows centering with feedback of offset in the x-y plane, while providing feedback of rotation about x, y, and z axis. Further, modifications to the present display can allow distinct, absolute and differential measurements of distance and rotation in separate axis (x, y and z), output to the user. It will be appreciated that because the magnetic flux lines lie in three dimensions the sensing device comprises a multi-axis positioning device. Further, the disclosed configuration of the sensor can compensate for constant, uniform (DC) magnetic fields that exist in the operating room (Earth's magnetic field, lights, instruments, etc.) but it is recommended that the operating table and other fixtures within an effective radius of the targeting magnet be non-ferrous.

Using the sensor array output, continuous feedback is provided for the surgeon to center the drill (not shown) in the drill sleeve **48** above the interlocking opening **14** in the medial plane. The positioning electronics, known to the art, are used to compare opposing sensor outputs and determine their location within the magnetic field, drive an LED display that visually indicates this position and perform calibration of the sensors **44**. It will be appreciated that the sensitivity of the device to movement is almost infinitely adjustable via the electronics.

The sensors **44** in the targeting array **42** should be sensitive to small changes in magnetic field, thereby making it possible to determine the position of the magnet in the field with a resolution of less than a millimeter in translation and less than one degree of rotation. Calibration is necessary because each sensor **44** has an inherent offset at zero field due to manufacturing tolerances. Additionally, it is necessary to null any extraneous fields present in the operating room. Circuitry, known to the art, is provided that zeros the output of each sensor so that the array is ready for targeting. Calibration must be done with the sensors **44** away from any strong magnetic field, including that of the target magnet **30**, so that the reading is not biased.

Once calibrated, it is possible to use the sensor array **42** to provide positioning data. When the array **42** is centered exactly over the target magnet **30** in the medial plane, all sensors **44a-h** will have equal voltage outputs. Any deviation from exact center, in either rotation or translation, will cause an offset in opposing members of the sensor pair. By comparing voltage offset between opposing sensors in the array, it can be determined which direction in the field they must be moved to have equivalent outputs. Those of skill in the art will appreciate that the sensor array must correspond to the magnetic field shape of the magnet to allow feedback of position about the desired axis for a specific application. It will also be appreciated that for any specific application, the magnet size and material may be changed, as long as the correct magnetic field shape is maintained.

In a more preferred embodiment, illustrated in **FIG. 5**, the outputs from the sensor array **42** are converted into a readable display **52** allowing the surgeon to precisely determine the location of the screw opening **14**. In this example, the display **52** resembles a "bull's-eye" of light emitting diodes (LED's) comprising a ring of red lights **54a-h** around a central green light **56**. Each LED is tied to the corresponding sensor **42a-h** in the elliptic array. If a sensor pair has a voltage difference between them, it will be indicated on the LED display **54a-h**. An illuminated red LED means that the target sensor **40** must be moved in the direction of the light. The position indicating LED's have a variable brightness which decrease as the target sensor **40** moves toward correct alignment. When all the target sensors **42a-h** are properly aligned, all of the red LED lights **54a-h** will shut off and the central green LED **56** will light up, indicating correct placement of the drill sleeve **48** for drilling the hole through the bone **20** and IMN opening **14**. In a further embodiment the sensor device circuitry can be adapted to provide visual audible, tactile, or other feedback mechanisms to indicate alignment.

While the operation of this invention should be self-explanatory from the foregoing description, a brief description of the procedure will now be presented. In order to align the drill bit with the axis of the desired interlocking hole, the surgeon must have feedback of positioning for rotation and translation in three dimensions. A coordinate axis is used where it is assumed that the axis of the interlocking opening **14** is z, and the x-y plane, normal to the face of the opening **14**, is coplanar with the medial plane. This is the direction from which the surgeon will be locating and drilling the hole in the bone. The magnet **30** and positioning device **40**, containing the sensing array **42** provide feedback for the surgeon to align the drill sleeve **48** so that it is parallel to the axis of the opening **14** for drilling. The magnet **30** is placed inside the IMN **10** at a point in front of the distal screw hole **14** to be targeted. The magnet **30** is inserted on a rod or wand **32** through the proximal opening (not shown) in the IMN **10**, while its insertion depth is fixed by a locking pin (not shown). Once the magnet **30** is placed at a fixed position next to one of the distal holes **12**, **14**, a skin incision is marked using the array of magnetic sensors to locate the position of the now-internal magnet **30** which projects central flux lines **50** parallel to the axis of the opening **14**. The targeting device **40** is used to locate the magnet **30** which is locked in place offset from the opening **14** to be drilled. The north pole of the magnet must face medially (along the z-axis **36**) so that it projects a magnetic field having a central line of flux parallel to the axis **39** of the interlocking opening **14**. From outside the extremity in which the IMN **10** is inserted, the targeting will be performed by an array of magnetic sensors **44** held parallel to the medial plane. These sensors **44** are embedded in the handle **46** of the targeting device **40**, which also includes the drill sleeve **48**. Acceptable drill sleeves have been developed previously that could be retrofitted to this design. The distance between the center axis **39** of the drill sleeve **48** and the center axis **37** of the magnetic sensor array **42** will be equivalent to the distance between the magnet **30** and the opening **14** inside the IMN **10**. When the sensor array **42** is aligned correctly over the magnet **30**, the drill sleeve **48** is aligned with the opening **14**. The drill sleeve is removable from the handle, so that the empty space can be used as a window to mark the skin to indicate the position of the internal target magnet for incision. The drill sleeve can then be replaced and the drill returned to position for the percutaneous procedure. The surgeon can advance the drill bit (not shown) through the bone without hitting the magnet **30**, while maintaining alignment feedback in real time. The actual locking mechanism is well known and can be retrofitted to the device of the present invention. An example of an acceptable locking mechanism can be found in *Durham and Crickenberger* (1998).

A readout on the handle **46** of the positioning device **40** will read a "bull's-eye" of LED's, which indicate correct position. The exterior display of sensors **44** will consist of a ring of red LED's, with one green LED in the center. The red LED's light to indicate which position the drill sleeve **48** must move to have correct alignment. When aligned correctly, all red LED's **44** will be off and the central green LED will be lit. The surgeon is then ready to drill the hole and insert the interlocking screws without aid of fluoroscopy or extraneous targeting systems.

Other embodiments and uses of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclose herein. All references cited herein for any reason, including all U.S. and foreign patents and patent applications, are specifically and entirely incorporated by reference. It is understood that the invention is not confined to the particular construction and arrangement of parts herein illustrated and described, but embraces such modified forms thereof as come within the scope of the following claims.

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CLAIMS

What is claimed is:

1. A device for detecting the location and position of interlocking transverse screw holes within an intramedullary nail for the internal fixation of long bones, the intramedullary nail having a longitudinal opening and transverse locking screw openings, comprising:
   a. a magnet adapted to be positioned within the longitudinal opening of the intramedullary nail for providing a directional field, wherein the magnet includes a three-dimensional orientation; and
   b. a positioning device, comprising:
      i. sensing means for identifying the magnet location along the three-dimensional orientation of the magnet, and
      ii. a drill sleeve.

2. The device of claim 1, wherein the magnet is slidably positioned within the longitudinal opening of the intramedullary nail.

3. The device of claim 2, wherein the magnet is attached to a wand for placement within the longitudinal opening of the intramedullary nail.

4. The device of claim 1, wherein the magnet includes a three-dimensional orientation along an x-axis, a y-axis and a z-axis, and wherein further the magnet comprises means to relate information about the three-dimensional orientation.

5. The device of claim 4, wherein the magnet is positioned such that the north pole of the magnet faces medially along the z-axis to project a magnetic field having a central line of flux parallel to the axis of the interlocking opening.

6. The device of claim 1, wherein the sensing means include means to provide sensing feedback for small variations of magnetic fields at a distance of 10 cm from the magnet.

7. The device of claim 1, wherein the sensing means comprises an array of at least two sensors.

8. The device of claim 7 further comprising eight sensors positioned in an elliptical array, wherein the eight sensors form four pairs of opposing sensors.

9. The device of claim 7, wherein each said sensor is oriented perpendicular to the flux lines that project radially outward from the magnet.

10. A method for positioning a locking screw at a desired concealed location within an external surface location, comprising:
   a. positioning a magnet within the concealed location, wherein the magnet includes a three-dimensional orientation;
   b. providing a positioning device external to the concealed location, wherein the positioning device comprises sensing means for identifying the magnet location along the three-dimensional orientation of the magnet, and a drill sleeve

comprising an axis intended for positioning at the concealed location; and

c. moving the positioning device along the external surface location until the sensing means senses the three-dimensional orientation of the magnet, wherein the axis of the drill sleeve is positioned at the concealed location.

11. The method of claim 10, wherein the magnet includes a three-dimensional orientation along an x-axis, a y-axis and a z-axis, wherein the z-axis is parallel to the drill sleeve axis, and wherein further the magnet comprises means to relate information about the three-dimensional orientation.

12. The method of claim 11, wherein the sensing means moves in a direction perpendicular to the z-axis.

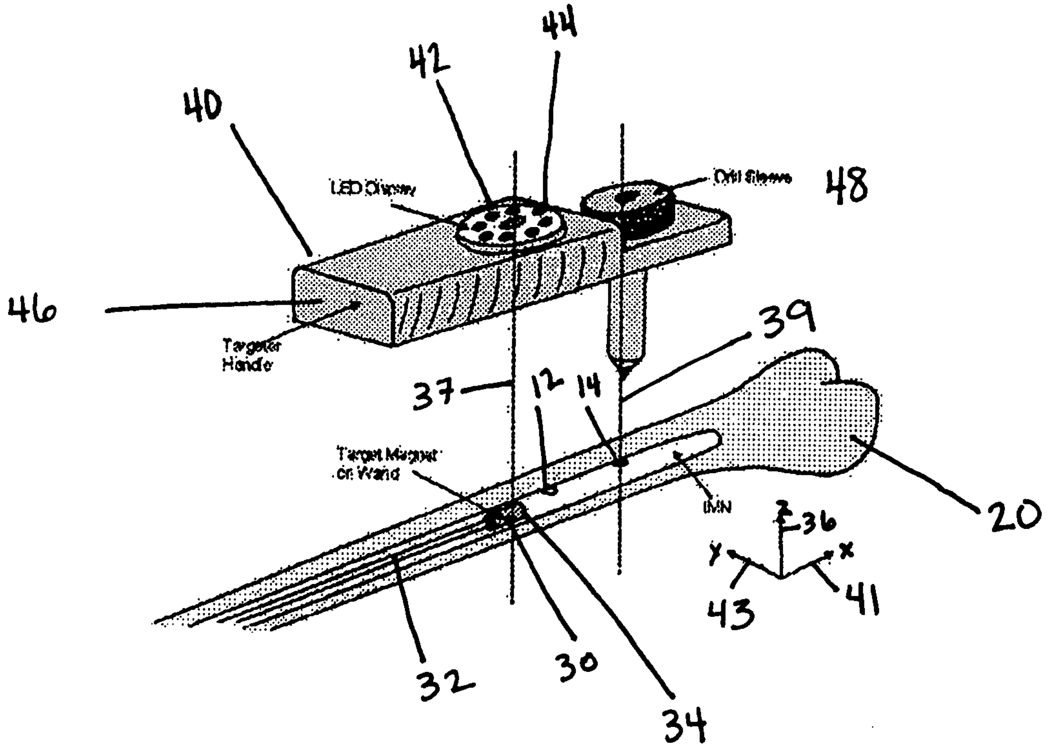
13. The method of claim 11, wherein the positioning device comprises at least two parallel-disposed sensors, which provide feedback as the positioning device moves along the external surface location.

14. The method of claim 13, wherein the positioning device comprises a sensing array of eight sensors positioned in an elliptical array, wherein the eight sensors form four pairs of sensors, wherein the sensing array moves in a plane perpendicular to the z-axis.

MAGNETIC TARGETING DEVICE APPLIED TO DISTAL INTERLOCKING OF INTRAMEDULLARY NAILS

ABSTRACT

A device and method for locating intramedullary screw holes is described. The device and method include a target magnet, which is inserted in the intramedullary nail (IMN), and a sensor comprising an elliptical array of magnetoresistive (MR) elements, designed to give information on the three dimensional orientation of the magnet. The sensor array is designed such that each MR element is a member of an opposing pair and relays information on their alignment with the target magnet. The array is connected to an LED display such that the position of the sensor in relation to the target magnet is easily discerned. The invention is lightweight and portable, capable of operating on batteries and can be used in primitive situations where a stable supply of electricity is not available.



LED Display
Drill Sleeve
Targeter Handle
Target Magnet on Wand
IMN
z
y
x

FIG. 1

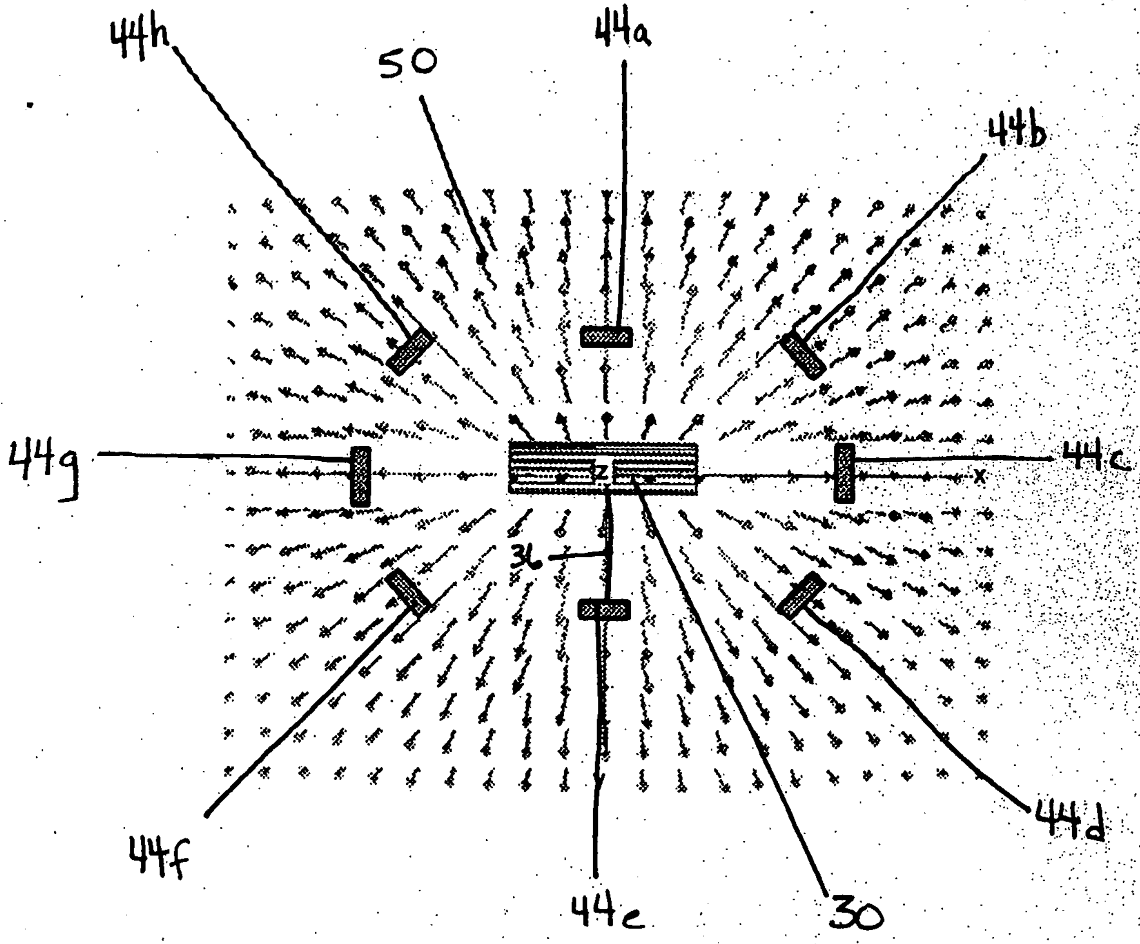


FIG. 2

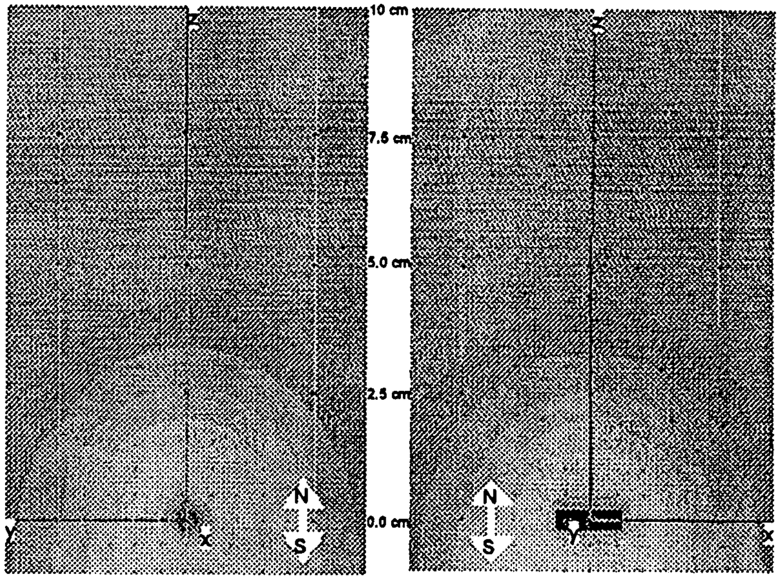


FIG. 3 a + b

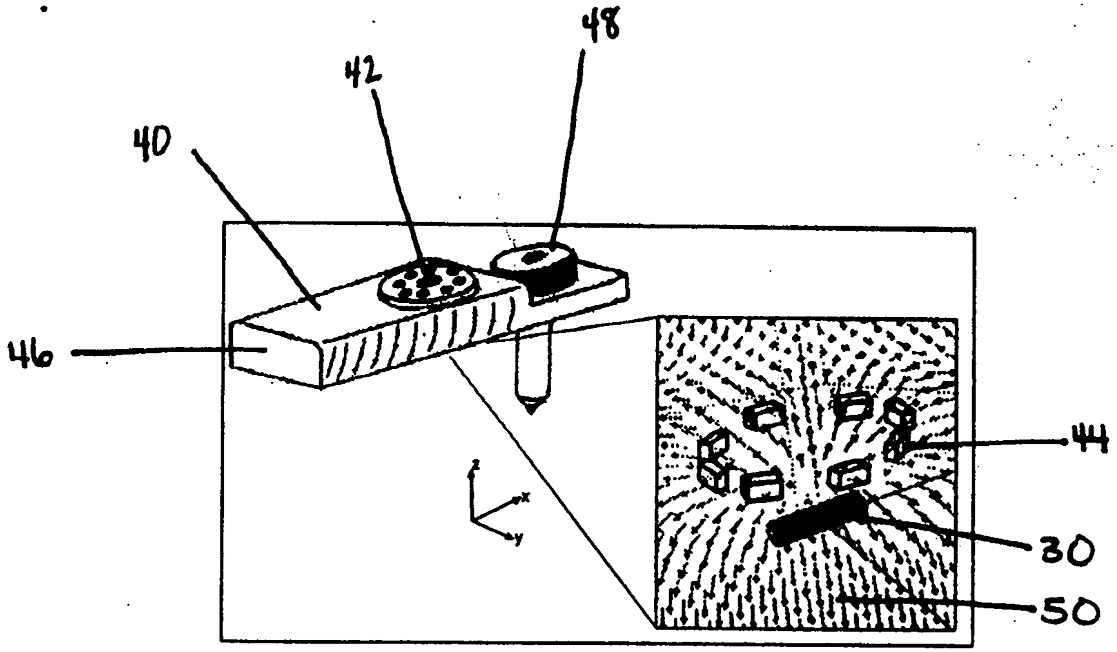


FIG. 4

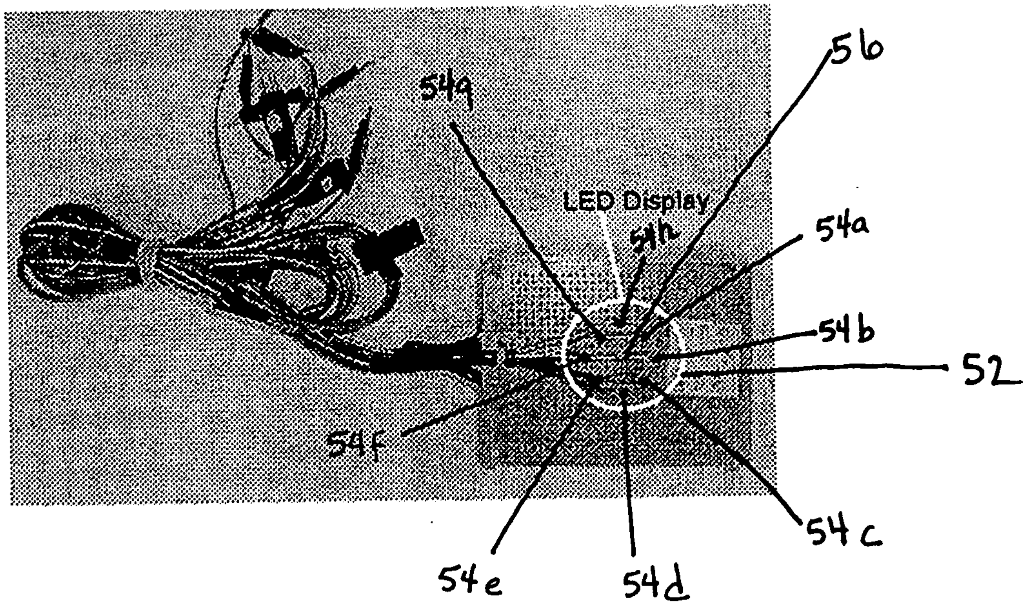


FIG. 5

United States Patent [19]

Brudermann

[11] **Patent Number:** **4,621,628**

[45] **Date of Patent:** **Nov. 11, 1986**

[54] **APPARATUS FOR LOCATING TRANSVERSE HOLES OF INTRAMEDULLARY IMPLANTATES**

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[73] Assignee: **ORTOPEDIA GmbH**, Kiel, Fed. Rep. of Germany

[21] Appl. No.: **648,015**

[22] Filed: **Sep. 6, 1984**

[30] **Foreign Application Priority Data**

Sep. 9, 1983 [DE] Fed. Rep. of Germany 3332642

[51] **Int. Cl.⁴** **A61F 5/04**
[52] **U.S. Cl.** .... **128/92 VD**; 128/92 R
[58] **Field of Search** .... 128/92 EB, 92 E, 92 R, 128/92 BC

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Primary Examiner—Gene Mancene
Assistant Examiner—C. W. Shedd
Attorney, Agent, or Firm—John P. White

[57] **ABSTRACT**

The apparatus serves to locate transverse holes V of intramedullary implantates, especially in the distal end of implanted interlocking nails, in the fracture treatment of bones. The apparatus includes at least one magnet (13, 16) generating an axially symmetrical field, and a magnetic field detection device (8, 9) having an axial reception characteristic, with one of said two directional elements being adapted to be aligned on the axis of the transverse hole (11) to be located. The other one of said two directional elements, e.g. the magnet (13), is freely movable exteriorly, and therefore adapted to be aligned with the axis of the transverse hole. The output signals of the magnetic field detection device (8, 9) are presented on a display device (17) through a signal processing device (15). By relative displacement of the magnet (13) and of the magnetic field detection device (8, 9), the two axes thereof may be made to coincide, which state can be displayed on the display device by a zero point indication.

22 Claims, 3 Drawing Figures

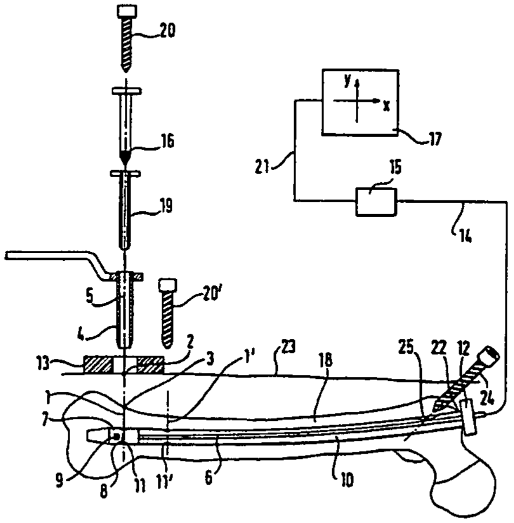


Fig.1

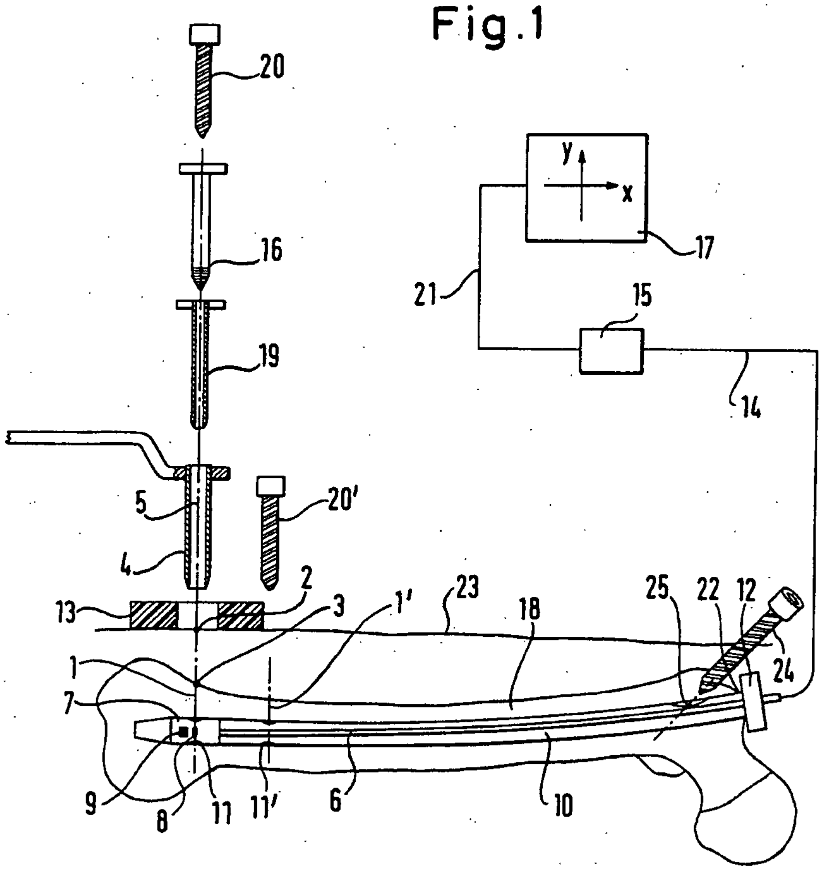


Fig.2

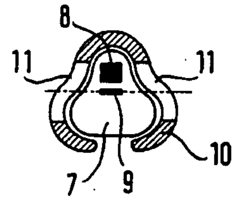
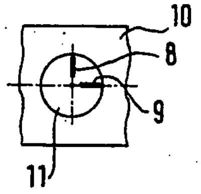


Fig.3



APPARATUS FOR LOCATING TRANSVERSE HOLES OF INTRAMEDULLARY IMPLANTATES

The present invention relates to an apparatus for locating transverse holes of intramedullary implantates in the fracture treatment of bones, especially for locating transverse holes in the distal end (remote from the body) of implanted interlocking nails, and for the coaxial alignment of a drilling device relative to these transverse holes.

Medullary spikes are used for the mutual intramedullary fixation of fragments of the long hollow bones in the fracture treatment thereof. A special construction of such spikes is provided with bores in both proximal, i.e. towards the body, and distal dispositions to extend transverse to the longitudinal axis of the spike, which bores serve to rigidly connect the bone fragments adjacent to the joint, upon insertion of these spikes, to the spike through auxiliary threaded bolts or pins, thereby to positively interlock their mutual positions relative to each other. This is expedient particularly in the case of multiple fractures, fragmental fractures or fractures with defect portions, and when treatment by means of external fixation elements, i.e. elements positioned on the outer side of the extremeties, is not necessary or advisable.

As the medullary canal of the long hollow bones, in general, neither has a constant cross-section along its full length, nor is linear, for the spiking of bones there are normally used spikes of such profile shapes which provide for a more or less definite geometrical matching of the spike with the configuration of the medullary canal when the spike is driven into the bone. The consequent is that these spikes are generally both twisted and bent when they are driven into the bone. Therefore, when the spike is driven in, the exact position of the distal end of the spike —when the latter is driven in from the proximal end in the usual way—cannot be determined precisely from the proximal end.

For the same reason, it cannot be foreseen, either, what exact position the distal holes (bores) of the spike will assume in the process of driving in, and where, accordingly, the holes have to be provided in the distal fragment of the bone in order to connect or lock the fragment to the spike transversely of the axis of the spike or bone with the aid of the abovementioned bolts or pins. However, these holes must be formed in the bone with a high degree of precision to prevent the metallic drilling chips are removed from the spike material at the edges of the transverse holes formed in the spike during the drilling operation. Otherwise, such drilling chips could remain in the intramedullary portion of the bone and thereby greatly affect in a negative sense the process of healing. For the same reason, simultaneous drilling of the distal holes in bone and spike must be avoided.

Various methods and devices are known for locating the distal holes, which are normally known as "distal location instruments". Below, the mode of operation of such instruments will be described briefly:

(1) For locating the proximal holes (bores), a mechanical location or finding instrument is used which is mechanically fixed to the proximal end of the spike. This location instrument includes a drilling jig which with a sufficient degree of precision aligns coaxially with the proximal hole of the spike being spaced only a few centimeters from the proximal end of the spike, even if the spike has suffered from deformation during the driving-in process. Heretofore, all of the conventional attempts to use location instruments operating in accordance with this principle also for locating the distal holes have failed, if they used such spikes which, in accordance with the original demand, were sufficiently resilient to conform themselves to the configuration of the medullary canal in the course of being driven into the bone.

(2) The use of bone spikes of an annular cross-section involves only the risk of bending of the spike, while rotational errors can be virtually avoided. In this instance, therefore, it is sufficient to determine the exact location of the spike end, since the variation of the spacing of the distal holes from the proximal end of the spike owing to the bending that has taken place is so small to be neglectible. To this end, location instruments are known which by means of magnetic coupling detect, and compensate for, the lateral deviation of the spike axis relative to the drilling direction. Here, the depth dimension of the hole to be drilled is insignificant, since the angular errors of the hole axis, as caused by bending of the spike, relative to the drilling axis are rather small. However, a location instrument of this type can be used only for spikes having a circular cross-section. On the other hand, spikes of this shape can conform themselves to the configuration of the medullary canal to a very low degree only, thereby not insignificantly reducing the strength of the system of the spiked bone.

(3) Another possibility consists in using still stiffer spikes than those mentioned above sub (2), but likewise with a circular cross-section. This would provide the advantage that a location instrument operating in accordance with the method explained above sub (1) might be employed, because bending of the spike during the driving-in process could thereby be avoided, too. In this instance, however, the drawbacks mentioned sub (2) become more prominent. Further, it is also of disadvantage that in this case the medullary canal must be enlarged by drilling to a substantially larger extent prior to insertion of the medullary spike, this resulting not only in the abovementioned disadvantages, but also in increased lesion of the bone substance.

(4) In order to avoid the discussed drawbacks, the most common practice is that the desired spikes—regardless of their kind—are initially driven in, and that thereafter the distal holes are located by means of an X-ray apparatus—generally termed image converter. In this case, the approximately point-shaped source of radiation must be positioned precisely in the direction of the extended axis of the distal hole to be located, which can be recognized from the shadows produced by the hole edges, since the circular hole appears on the screen as a circle only when this position is reached. There are already known location instruments which are mechanically connected to the image converter in such a manner that a drilling jig may be attached thereto upon locating the correct position, with the axis of the drilling jig being aligned with the axis of the hole. However, the accurate positioning of the large and heavy image converter is difficult and troublesome, and the fixation of the image converter relative to the spike and the bone is likewise difficult. Furthermore, however, a serious disadvantage of these conventional instruments is the radiation effect on both the medical personnel and the patent during the positioning and fixation of the drilling jig. Finally, the production of the holes in the

bone by means of drills used to this end likewise constitutes an inconvenient and uncertain method.

(5) Therefore, location instruments of the last-described type are seldom used in practice; rather, the piercing or puncture point of the hole through the surface of the skin is marked by means of the pointed end of a scalpel placed in the optical path of the image converter, whereupon the image converter is moved away from the field of operation. Subsequently, the scalpel is used for the incision of the soft tissue, a drilling jig is inserted into, and thereafter the hole is formed in the bone as estimated by the eye. However, this most commonly used method at the same time increases the radiation effect on the operator, as compared with the method discussed above sub (4), while also substantially increasing the risk of inaccurate drilling. Then, drilling errors must be tolerated, and re-drilling or re-adjustment is not possible; and, as an inevitable consequence, metallic chips of the spike material enter the medullary canal. Further, a proper fit of the transverse bolts along with the orderly fixation of the bone fragments which depends on such fit, can hardly be obtained.

It is the object of the present invention to provide an apparatus for locating transverse holes (bores) of intramedullary implantates, particularly of the distal holes of interlocking nails, which apparatus permits the fast, convenient and secure placement of the drilling jig in axial alignment with the transverse holes, without involving a radiation effect on the surgeon and the medical personnel.

According to the present invention, this object is solved in that at least a first directional element in the form of a magnet producing a directional field, and a second directional element in the form of a magnetic field detection device with unidirectional reception characteristic are provided; that one of said two directional elements is adapted to be aligned with an excellent or predetermined receive direction to the axis of the transverse hole to be located; that the other directional element is freely movable, and that the output signals of the magnetic field detection device are fed, through a signal processing device, to a display device displaying the relative position of the directional characteristics of said two directional elements to each other. Preferably, the magnetic directional field is oriented in an axially or rotationally symmetrical fashion.

Thus, in the apparatus according to the invention the directional characteristics of the magnetic field and of the magnetic field detection device are used to control the relative positions of the axes of both directional elements through a display device, such that both axes may be brought into congruence with each other by means of this control display. One of said two directional elements is aligned exactly with the axis of the transverse hole, by, for example, mechanical means disposed interiorly of the implantate, while the other, exteriorly disposed directional element may be used for marking the located hole, such as on the skin, or for positioning a drilling jig.

In order to reduce detection errors, the locating process may be effected by two independent detection steps in which two points of the axis of a transverse hole in the implantate are found or located, which clearly define the position of this axis. Hereby, it is expedient that, perhaps, two diferent movable directional elements are provided, one of which is useful, for example, for finding a point on the body surface, and a second one of which is suitable for finding a point directly on the surface of the bone.

Optionally, the pair of directional elements may be formed and arranged such that, in the one instance, the magnetic field detection device is linked to the axis of the transverse hole in the implantate and the magnet is movably positioned exteriorly, and that, in the other instance, the axis of the transverse hole in the implantate is linked to the magnetic field or the magnet, respectively, and the magnetic field detection device is movable exteriorly.

For generating the magnetic field, there may be used, for example, a permanent magnet or even an electromagnet. Expediently, the magnetic field detection device is provided with one or more magnetically controllable semiconductor elements, with the use of Hall elements being particularly advantageous. However, field plates or other elements may be used while obtaining equivalent effects.

The magnetic field detection device may be arranged such that the maximum of its detection sensitivity coincides respectively with the axis linked to its directional characteristic, such that this axis may be determined by finding the signal maximum. In another advantageous embodiment, the magnetic field detection device is linked to the axis of the respective directional element in such a manner that this axis coincides with the minimum of its directional characteristic, such that the location of this axis may be determined by finding the signal minimum. As mentioned above, there may be determined, for example, two successive search points (positions) on the axis of the transverse hole of the implantate, with the first point being the piercing point of this axis through the surface of the skin and at the same time marking the penetration position for the necessary puncture incision through the soft tissue up to the bone, and with the second search point being defined on the surface of the bone after the effected puncture incision. Thus, expediently an annular magnet may be used for generating the magnetic field, which magnetic facilitates easy marking of the first search point on the skin surface. Upon insertion of a drilling jig into the puncture incision, another magnet in the form of a magnetic probe may be inserted into this drilling jig, which probe permits to precisely define the second search point on the bone surface.

In an expedient embodiment, the positioning of the one directional element on axis of the transverse hole in the implantate may be rendered possible in that one of the directional elements is mounted to the head of the probe to be inserted into the implantate having a cross-section contour, with the probe head being adapted to be positioned with a reproducible spacing from the accessible end of the implantate. Here, the probe may include an adjustable stop member for positioning the probe head in correspondence with the varying spacing of the transverse hole from the accessible end of the implantate, which spacing, however, is known in each individual instance.

A possible angular deviation of the directional characteristic of the probe relative to the axis of the transverse hole in the implantate may be prevented from occurring when the probe head is conformed to the inner contour of the implantate and adapted to be positioned within the latter, as a guide means, with its directional characteristic lying coaxially to the transverse hole.

Expediently, the signal processing device includes means for zero balancing in order to compensate magnetic stray fields, such as, for example, the earth magnetic field, prior to the start of the detection. As a display device, in most instances there would be used an optical display device, such as the monitor of an image converter, which is anyhow present in the operating theater. Further, there may be used also other optical display devices, and even acoustic signalling devices or signalling devices alarming other sense organs.

Below, the invention is explained in greater detail in one embodiment thereof with reference to the enclosed drawing, wherein:

FIG. 1 shows the positioning of an apparatus according to the present invention on an implanted interlocking nail;

FIG. 2 is a cross-sectional view of an interlocking nail at the level of a transverse hole, with the magnetic field detection device inserted therein; and

FIG. 3 is a side elevational view of an interlocking nail, as seen in the axial direction of the transverse hole, with the magnetic field detection device inserted therein.

FIG. 1 illustrates the positioning of an interlocking nail 10 in the medullary canal of a bone 18 situated with its certain spacing below the skin or body surface 23. In FIG. 1, the spike has been driven into the bone from the right side, and the spike has in the vicinity of its left, i.e. distal, end a pair of transverse holes 11 and 11' for receiving transverse bolts 20 and 20', respectively.

Now, the exact position of the respective drilling axis 1 of a distal hole 11 in the interlocking (medullary) spike 18 is to be determined. This drilling axis may be definitely determined by a linear connecting line of two points 2 and 3 on this axis. In order to place a drilling jig 4 in a position aligned with this axis, the two points 2 and 3 on the drilling axis of the distal hole 11 must be located accordingly, and the axis of the drilling jig must be oriented in accordance with these points, whereupon the hole (bore) may be formed in the bone immediately. The first one (2) of these two points is determined on the skin surface 23, to thereby at the same time define the locus of the puncture incision. The second point 3 is determined on the surface of the outer cortex and, thus, at the same time provides the location on the bone through which the drill must pass. Here, the puncture incision made through the first point 2 and extending up to the bone, sumultaneously receives the drilling jig 4 the axis 5 of which, thus, extends through the initially found point 2.

The apparatus according to the invention is used for locating these two points 2 and 3, and this apparatus includes a magnetic field detection device in the form of a probe 6 including a probe head 7 and Hall elements 8 and 9 mounted thereon. Here, these two Hall elements 8 and 9 are mounted in such a manner that their principal planes intersect each other on the axis 1 of the distal hole 11. This axis 1 is the geometrical locus of all points (locations) where an axially symmetrically applied magnetic field does not generate any output signals on both Hall elements. This is achieved in that the probe head 7, as shown in FIG. 2, is formed as a shaped part conformed to the inner contour of the spike 10; accordingly, this probe head, during insertion of the probe 6, is guided in the interior of the, here trifoliate, cross-section of the spike 10, even if the spike 10 during driving in thereof has suffered from bending and/or twisting of some realistic kind. The exact orientation of the probe head 7 or of the Hall generators 8 and 9 in the longitudinal direction of the spike 10 relative to the axis of the transverse hole 11 is obtained by the fact that the spacing of the transverse hole 11 from the proximal end 22 of the spike 10, with a realistically pronounced deformation and in consideration of the elastic deformability of the probe 6 in the shank thereof, is maintained with a sufficient degree of accuracy. For varying lengths of spikes or for the various distal holes 11 or 11' of the spike 10, a stop member 12 may be positioned and fixed on the probe shank 6 in correspondingly different positions prior to inserting the spike into the bone. Correspondingly differently shaped probe heads 7 are required for different spike diameters or different profile (cross-sectional) shapes of the spike, respectively.

The illustrated apparatus further comprises a search magnet in the form of an annular magnet 13, and a bar magnet 16. For forming the hole (bore), the above described drilling jig 4 in combination with an auxiliary insert 19 is used.

The output signals of the Hall elements 8 and 9 are led through a line 14 to a signal processing device 15 by which the Hall elements are also supplied with electric power in the customary manner. The output signals of the processing device 15 are fed through a line 21 to a display device 17 on which, then, the respective relative positions of the axes of the magnetic field detection device on the one hand and of the respectively employed magnet 13 or 16 on the other hand are visualized.

Prior to starting the detection, balancing of the display is necessary. To this end, the search magnets 13 and 16 must be held remote from the assembly such that the zero point of the display unit 17 may be balanced in order to thereby compensate for the effects to the earth magnetic field and other stationary stray fields. For performing the searching operation proper, the annular magnet 13 is then placed in the vicinity of the Hall elements 8 and 9, and moved on the skin surface 23. The display deviates from the value set by zero balance as long as the magnetic field of the annular magnet 13 applied at the locus of the Hall elements is directed so as to have at this locus a magnetic field strength vector which is not directed in parallel with the pair of Hall elements.

With a suitable magnetization of the annular magnet 13, the magnetic flux lines thereof in the immediate vicinity of its axis of rotation are linear and parallel to this axis. When the axis of rotation of the annular magnet 13 is positioned approximately normal to the longitudinal axis of the spike 10 in the region of the probe head 7, the output signals of the pair of Hall elements 8 and 9 only re-assume the value set by the zero balancing of the signal processing device 15 when the axis of rotation of the annular magnet 13 and the axis of the hole 11 are aligned with each other with sufficient accuracy. Accordingly, the piercing point of the axis of rotation of the annular magnet 13 through the skin surface 23 of the patient is at the same time the first point 2 to be found. This point may be fixed as the center point of the opening of the annular magnet 13, and marked on the surface of the skin.

In the described procedure, the not completely linear configuration of the magnetic flux lines of the annular magnet 13 outside of its axis of rotation may give rise to an angular error the tangent of which might result in a misdrilling at the locus of the bone, if the drilling jig 4 were adjusted exclusively in accordance with the position of the annular magnet 13 upon reaching the set zero value.

For this reason, the apparatus is provided with a second magnet 16 in the form of a pin-shaped magnetic probe by means of which a second search operation may be performed. To this end, when the puncture incision has been made, the drilling jig 4 is inserted into the anyhow required puncture through the soft tissue surrounding the bone, with the end of this drilling jig remote from the bone being retained with adequate accuracy at the point 2 by the skin incision defined according to the first search operation. Owing to a certain elasticity of the soft tissue, the bone-side end of the drilling jig 4 may be slightly moved in tangential direction on the bone surface.

Now, the magnetic probe 16 is inserted into this drilling jig 4, which probe has its shape conformed to the inner diameter of the drilling jig and is magnetized so as to generate a magnetic field the flux lines of which, in the region of the axis, extend linearly with sufficient exactness, and in parallel with this axis. Principally, the search operation is performed in the same manner as the above described first search operation, whereby the bone-side end of the drilling jig is brought into a sufficiently exact position centrally relative to the considered hole 11 in the spike 10, by slightly moving or displacing this end on the bone surface. In this operation, the end of the drilling jig remote from the bone is held on the previously defined search point 2 with a sufficient degree of accuracy.

In this position of the drilling jig 4, upon removal of the magnetic probe 16 the drilling insert 19 may be inserted, while at the same time removing the Hall probe 6 from the spike 10. Then, the bone 18 may be rough-drilled through the insert 19; subsequently, the insert 19 is removed again, and the cortex of the bone 18 adjacent the drilling jig 4 is drilled out to a larger diameter to receive the bolt shank of the (threaded) bolt 20. The hole formed initially with the use of the insert 19 also in the opposite cortex has its previous diameter unvaried, to receive the threads of the bolt 20. Thereafter, the drill and the drilling jig are removed, and the locking bolts 20 are inserted into the drilled hole.

After to performing the above operations at the distal end, the proximal bolt 24 is to be placed into the corresponding hole (bore) 25, and this operation need not be described in greater detail here since, owing to the small distance to the proximal end of the spike, a conventional location and drilling device as described sub (1) in the introductory part may be used with a sufficient degree of precision for the locating of the proximal holes.

When using the apparatus according to the invention, thus, the usual implantates and the conventional instruments for operation in the proximal region may be used as before. Principally, this applies also to the operations performed in the distal region. For example, the implantate material of the spike 10 and of the bolts 20 may be used in the conventional form, same as the drilling jig 5 and the insert 19. The present location or finding apparatus including the probe 6 and the probe head 7, the two magnets 13 and 16 as well as the signal processing device 15 and the display device 17 may be employed in addition to the conventional instruments. In the conventional instruments, care must only be taken that the drilling jig 4 and the insert 19 are be formed of non-magnetic material. This requirement anyhow applies to implantates because of regulations concerning implantate materials.

Supplementarily, it may be noted further that the apparatus is capable of operating effectively even if the probe head cannot be guided by the inner profile of the implantate, such as, for example, in the case of spikes having a circular cross-section. In such instance, auxiliary measures may be taken in order to align or orient the probe head relative to the transverse hole. For example, this may be effected with the aid of a holding device adapted to engage into the hole.

I claim:

1. An apparatus for positioning a drilling jig in axial alignment with at least one predisposed transverse hole in an implanted intramedullary nail, said apparatus comprising at least a first directional element in the form of a magnet (13,16) producing a directional field, and a second directional element in the form of a magnetic field detection device (8,9) with unidirectional reception characteristic; wherein one of said two directional elements is adapted to be aligned with a directional pattern thereof to the axis of the transverse hole (11) to be located, and the other directional element is freely movable; and the output signals of the magnetic field detection device (8,9) are fed, through a signal evaluation and processing device (15), to a display device (17) displaying the relative position of the directional characteristics of said two directional elements to each other.

2. The apparatus according to claim 1, characterized in that at least two freely movable directional elements (13, 16) are provided, which are adapted to be placed to different positions of a body.

3. The apparatus according to claims 1 or 2, characterized in that the magnetic field detection device (8, 9) is adapted to be aligned on the axis of the transverse hole (11) of the implantate (10), and that the magnet (13, 16) is freely movable.

4. The apparatus according to claims 1 or 2, characterized in that the magnet is adapted to be aligned on the axis of the transverse hole, and that the magnetic field detection device is freely movable.

5. The apparatus according to claim 1, characterized in that the first directional element is a permanent magnet (13, 16).

6. The apparatus according to claim 1, characterized in that the first directional element is an electromagnet.

7. The apparatus according to claim 1, characterized in that the magnetic field detection device includes one or more magnetically controllable semiconductor elements (8, 9).

8. The apparatus according to claim 7, characterized in that the magnetic field detection device includes one or more Hall generators (8, 9).

9. The apparatus according to claim 1, characterized in that the magnetic field detection device has the maximum of its detection sensitivity in (on) the axis of its directional characteristic.

10. The apparatus according to claim 1, characterized in that the directive axis of the magnetic field detection device coincides with the minimum of the reception characteristic thereof.

11. An apparatus according to claim 1, characterized in that a pair of Hall generators (8, 9) are positioned in the magnetic field detection device under such angles that their two principal planes intersect each other on the directive axis of the magnetic field detection device.

12. The apparatus according to claim 11, characterized in that said two Hall generators (8, 9) are positioned under right angles to each other.

13. The apparatus according to claim 1, characterized in that an annular magnet (13) serves as the first directional element.

14. The apparatus according to claim 1, characterized in that a magnetic probe (16) adapted to be inserted into a drilling jig (4) serves as the first directional element.

15. The apparatus according to claim 1, characterized in that one of said directional elements (8, 9) is mounted to the head (7) of a probe (6) adapted to be inserted into the implantate (10) having a hollow profile, with the probe head (7) being adapted to be positioned with a reproducible spacing from the accessible end (22) of the implantate (10).

16. The apparatus according to claim 15, characterized in that the probe (16) includes an adjustable stop member (12) allowing for different positioning of the probe head (7).

17. The apparatus according to claim 1, characterized in that the probe head (7) is conformed to the inner profile of the implantate (10) and, with this structure, adapted to be positioned with its directional characteristic coaxially to the transverse hole (11).

18. The apparatus according to claim 1, characterized in that balancing means for the compensation of magnetic stray fields is provided in the signal evaluation device (15).

19. The apparatus according to claim 1, characterized in that the signal evaluation device (15) converts the output signals for presentation on an optical display device (7).

20. The apparatus according to claim 19, characterized in that a conventional monitor may be used as the display device.

21. The apparatus according to claim 1, characterized in that a signalling device alarming the ear or a different human sense organ is provided as said display device.

22. The apparatus according to claim 1, characterized in that the directional field of the magnet (13, 16) is an axially or rotationally symmetrical magnetic field, respectively.

* * * * *

CONFIDENTIAL
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DISCLOSURE NO. 02.082

VIRGINIA TECH INTELLECTUAL PROPERTY DISCLOSURE

NOTE: Intellectual property disclosures are treated as confidential information. Except for individuals engaged in the evaluation and approval process, the information will not be divulged to others without the permission of the originator(s), except as required by law.

1. TITLE OF WORK: Magnetic targeting device applied to interlocking of distal intramedullary nail screw holes

2. TYPE OF WORK: Invention X Software ___ Book ___ Article ___
Video ___ Film ___ Other ___ (Describe)

3. LIST OF ORIGINATORS (authors, inventors, creators or other contributors) of the work.

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Please attach a separate page for additional originators, if needed.

PENGAD 800-631-6989
EXHIBIT
B

4. FUNDING SOURCES FOR THE CREATION OF THE INTELLECTUAL PROPERTY.

Funding for the creation of Intellectual Properties may come from a variety of sources, e.g. sponsored research contracts, foundation grants, etc. Funding often carries obligations to the sponsor, and may give the sponsor certain rights to the work. Thus it is important that you identify all sources of funding that supported creation of this IP, whether internal or external.

Did you receive any financial support for the development of this intellectual property?
_X_ Yes __ No If yes, complete the appropriate blanks below.

a. Name of sponsoring organization(s):
Carilion Biomedical Institute

b. Funding Period: Start: __August 2001______ End: __June 2003______

c. If a sponsored grant or project, provide the Virginia Tech Grant or Project No. and a copy of the sponsor agreement:
4-33904

5. SPONSOR RIGHTS

As far as you know, does the sponsor(s) have any claims to the Intellectual Property?

_X_ Yes ____ No If yes, please indicate the nature of these commitments and attach a copy of the agreement.

Refer to existing Carilion Biomedical Institute intellectual property agreements with Virginia Tech and UVA.

ASSIGNMENT OF OWNERSHIP

Under ordinary circumstances, Intellectual Properties developed with sponsored funds are owned by the university and the creators are obligated to assign their rights to Virginia Tech. This assignment gives VTIP the authority to act on behalf of the creators and Virginia Tech to pursue the protection, marketing and commercial development of the property. (Creators receive 50% of any net royalties.) Use Attachment A for assignment of ownership to Virginia Tech.

Creators may be entitled to claim ownership of certain categories of Intellectual Property. This may be the case if no university resources were used in creation of the Intellectual Property, or if the property meets the definition of a traditional work of academic scholarship as described in Policy 13,000, Section 2.4.A. If you wish to make a claim of creator ownership, you should request a determination of ownership by the Intellectual Property Committee. Contact the Chair of the Intellectual Property Committee in the Office of Program Development, Division of Research and Graduate Studies for further details on how to request such a determination.

DESCRIPTION OF THE INTELLECTUAL PROPERTY

(Throughout the rest of the disclosure form, please answer all the questions that apply to your form of Intellectual Property.)

1. If you are submitting an INVENTION, is it a new process, composition of matter, device or one or more products for a new use, or an improvement to an existing product or process?

This is a new prototype device. It is meant to enhance and/or replace existing technology used to target and drill distal intramedullary nail (IMN) screw holes.

2. If this is a COPYRIGHT WORK or TRADE MARK, describe the content or attach a copy. Software, depending upon its nature and function, may be protected either by patent or copyright. VTIP can help you decide which route is best in your case.

3. DESCRIPTION OF EVENTS (Complete for INVENTIONS.)
This information is important for deciding priority of invention and/or legal "bars" to patenting. In general, publications, in any medium, before the date a formal patent application is filed in a national patent office can cause **loss of foreign patent rights.** U.S. law allows inventors up to one year to file a patent application after first public disclosure, use or sale.

EVENTS	DATE	INDICATE THE WRITTEN RECORD (e.g., notebook, letter, email). IF ORAL DISCLOSURE, INDICATE TO WHOM
Initial conception of the idea	DATES REDACTED	Written sketch of idea in class notes. Discussion between originators.
First description of complete invention, oral or written		Discussions with Dr. Durham, Dr. Wicks, and David Szakelyhidi
First successful demonstration (first actual reduction to practice)		Tested targeting feedback of prototype device using test fixture for positioning.
Has this work been: i. Submitted for publication? Y [✓ N] ii. Accepted for publication? Y [✓ N] iii. Published? Y [✓ N]	No	None
Have you presented this work at a conference or meeting? i. Did you submit an abstract? Y [✓ N] ii. Was an abstract published? Y [✓ N] iii. Did you use handouts? Y [✓ N]	No	NAME OF CONFERENCE OR MEETING None
Have you submitted this work for presentation at a conference or meeting? Y [✓ N]	No	None
Have any portions of this work been posted on a public web page?	No	GIVE WEB PAGE ADDRESS

4. If an INVENTION, provide a complete description and identify and describe the novel or unusual features. Use extra sheets or attachments if necessary.

The device functions as a precision magnetic targeter which provides visual feedback of alignment. It uses a permanent magnet and magnetic sensors which can be used to align a drill bit so that it is parallel to the axis of the hole for drilling IMN interlocking screw holes. The novel features of this device include the following:

- No active or passive electronics in vivo
- No x-ray imaging needed for targeting
- Single target magnet with unique axisymmetric field
- Real time feedback of alignment
- Adjustable sensitivity
- Visual, audible, or tactile positioning feedback is possible
- Novel magnet orientation

(See Attachment D for a more detailed description of the prototype device.)

5. What is the existing technology/art to which you are comparing?

This new prototype device is an enhancement and/or replacement of existing devices used to aid orthopedic surgeons in targeting and drilling distal interlocking IMN screw holes. These include devices which use x-ray, mechanical, or magnetic means of targeting. Examples of existing devices are described in the paper presented in Attachment D.

6. How does your INVENTION differ from present technology, what problems does it solve, or what advantages does it possess? (This should be written so someone skilled in the art can understand it.)

This new prototype device has significant advantages over existing devices, including the following:

- No active or passive electronics in vivo
- No x-ray imaging needed for targeting
- Real time feedback of alignment
- Percutaneous technique
- Low power requirements allowing battery operation
- Can be adapted for use with existing IMN's

(These advantages are described in detail in the paper presented in Attachment D.)

7. If not indicated previously, what are the possible uses and markets of the INTELLECTUAL PROPERTY? In addition to immediate applications, are there other uses that might be realized in the future?

This prototype magnetic targeting device can improve orthopedic surgeons' ability to target and drill distal IMN interlocking screw holes. The stated device has significant advantages (as stated in questions 5and 6) that will appeal to orthopedic surgeons that perform IMN insertions and interlocking. This device also has applications for positioning and aligning tools and instruments with great accuracy during various medical procedures. This targeting could also be applied to industry, where the relative position of objects must be known when visibility is obstructed.

Attach sketches, drawings, photographs, and other materials that may help illustrate the description. Rough art work, flow sheets, Polaroid photographs, and penciled graphs are satisfactory as long as they tell a clear and understandable story. (See Attachment D)

OTHER PERTINENT DATA

1. Is a publication or oral disclosure descriptive of the INVENTION planned within the next six months? Give date (estimate, if unknown) and attach copies of any existing manuscripts, preprints, or abstracts.

When provisional patent is in place, this prototype device will be presented in a graduate thesis, medical journal, and engineering journal.

2. Has the INVENTION been tested experimentally? __X__ Yes ____________ No
Are experimental data available? __X__ Yes ____________ No
If possible, attach a copy of the key experimental results. If necessary, who should be contacted for access to the data?

For experimental data, please contact:
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Blacksburg, VA 24061-0238
Phone: (540) 231-1271
Fax: (540) 231-9100
Email: dszakely@vt.edu

3. Are there known INVENTIONS by others that are related to this one? Please describe, including literature references to relevant patents and publications that most closely describe the state of the related art prior to your invention.

The most closely related devices are found as previously filed patents. U.S. Patent number 5049151 by Durham et al, describes a device which uses the attraction between an internal and external magnet to align a drill sleeve with the IMN distal interlocking screw hole for drilling. U.S. Patent 6162228 by Durham follows this idea by including magnetic sensors and an electronic system to indicate alignment of the magnet and interlocking hole. U.S. Patent 5411503 by Hollstien describes a device which uses magnetic sensors to target an internally placed magnet to align a drill sleeve with the interlocking hole. Additional devices related to this new prototype device are described and referenced in the paper in Attachment D.

Has the INTELLECTUAL PROPERTY been disclosed to industry representatives? ____ Yes _X_ No
Has any commercial interest been shown in it? _X_ Yes ___ No
Do you know of any other firms that might be interested in the materials? _X_ Yes ____ No
Name companies and specific individuals and their titles, if you can.

Carilion Biomedical Institute, George Blanar, Vice President for Business Development
Refer to their marketing evaluation.

4. Please list any companies and/or individuals you do not wish to be contacted regarding this technology.

EVALUATION OF THE INTELLECTUAL PROPERTY

1. Please describe briefly the impact this INTELLECTUAL PROPERTY is likely to have on the field of endeavor (i.e., marginal improvement, significant change, revolutionary upheaval, creates new field, etc.) and why.

   This new prototype device is likely to cause a significant change in the way orthopedic surgeons perform distal interlocking of IMN's. This device can provide feedback of distal interlocking screw hole alignment for drilling with significant advantages over current systems. It uses no x-ray for targeting, is percutaneous, low power, has no active or passive electronics in vivo, and gives real time feedback of alignment.
   (Refer to question 6)

2. Please describe briefly the stage of development of the INTELLECTUAL PROPERTY (i.e., conceptual idea, theoretical design, prototype, complete product/process, outline, rough draft, finished work of authorship, ready for commercial testing/marketing, etc.) and give an estimate of the nature and amount of work that still remains to be done before a commercial venture/product is obtained.

This new device exists as a prototype magnetic targeter (See Attachment D). A minimal amount of work is required to adapt this prototype for use in the operating room. The electronics must be miniaturized, and a sterilizable housing and drill sleeve created for the final device. The novel magnetic targeting approach is complete and the necessary additions can be adapted from pre-existing parts. This finalization could be outsourced to a company with the necessary facilities for development of medical devices. The total work required to bring the prototype to marketability would take less than a year.

3. Please give your best guess as to the economic potential of this INTELLECTUAL PROPERTY if successfully commercialized, in terms of annual revenues: Less than $10,000 ____ $10-$100,000 ____ $100,000-$1 million _X_ Over $1 million ____

4. If the INTELLECTUAL PROPERTY is of a type on which patent(s) may be pursued, do you consider it worthwhile to spend up to $10,000 to obtain a U.S. Patent? _X_ Yes ____ No
   Please indicate the reason(s) for your response.

This device has the ability to make a significant contribution to orthopedic surgeries involving IMN interlocking. Approximately 30,000 of these surgeries are performed each year, providing a larger market for the device. This new device has advantages that can alleviate many problems that may arise during IMN distal interlocking.

Please list individuals (both on and/or off campus) with technical or economic knowledge in the field of the INTELLECTUAL PROPERTY who could be asked (under confidentially undertakings if necessary) to review, assess, or evaluate the technical and commercial potential of this INTELLECTUAL PROPERTY.

Company and Contact Name	Company Address or contact information
David Szakelyhidi Virginia Tech	144 OPP Randolph Hall, Blacksburg, Va. 24061-0238 dszakely@vt.edu 540-231-1271
Dr. Al Wicks Virginia Tech	144 U Randolph Hall, Blacksburg, Va. 24061-0238 awicks@vt.edu 540-231-4323
Dr. Al Durham Orthopedic Surgery of Roanoke	2110 Carolina Ave. SW, Roanoke, Va. 24014 concepgen@aol.com 540-345-4907

5. Please give us any other pertinent comments not covered elsewhere that may provide guidance to the decision-making process and optimal utilization of the INTELLECTUAL PROPERTY.

This disclosure is a replacement of the previous VTIP disclosure number 01-030, submitted by the same originators.

Please contact Carilion Biomedical Institute for filing of provisional patent.

Signature(s) of Originators:

a. ______________________

b. ______________________

c. ______________________

d. ______________________

e. ______________________

DATES REDACTED

Signature of Principal Investigator

Provide the name and signature of the Principal Investigator (if sponsored project funding was involved in development of work).

(Please type or print name and title)

Dr. A. Wicks — Associate Professor

Name — Title

______________________ DATE REDACTED

Signature — Date

Name and signature of Department Head, Division Director, and/or Center Director of the originators, contributors, inventors or authors.

If more than one department or unit was involved, each unit head should answer the questions and sign with respect to members of that unit.

Please answer the following questions for all originators that work in your Department, Division or Center. This information may be important in case there are questions regarding ownership of the INTELLECTUAL PROPERTY described, or of eligibility for revenue sharing.

1. Were University resources, such as facilities, equipment, materials, funds, information, or the time or services of other University employees, used in the production of the work or development of the INTELLECTUAL PROPERTY? X Yes ______ No
2. Does the work performed in the development of this INTELLECTUAL PROPERTY fall within the range of the normal activities expected of the originators by their appointment or employment by VIRGINIA TECH (i.e., teaching, research, public service, etc.) X Yes X No
   If No, please describe why the work falls outside normal activities. please see attachment E
3. Was the work specifically and explicitly assigned to the employee(s) by your unit? X Yes X No
   (See University Policy 13,000 on Intellectual Properties, Sec. 2.4.C.2.a & b)
   please see attachment E
4. Did the originators work on this project during their normal University working hours? X Yes X No
   please see attachment E

(Please type or print name and title.)

Walter O'Brien Dept. Head, ME

Name Title Department/Division/Center

Walter F O'B

Signature

DATE REDACTED

Date

NOTE: If Dept. Head is a co-inventor, the Dept. Head's administrative supervisor must sign this form

(Please type or print name and title)

____

Name Title Department/Division/Center

____

Signature Date

NOTE: Should any royalties be earned from this disclosure, the Department is entitled to a 10% share. Please indicate the departmental account number that should receive these funds.

Departmental Account Number: 881251

(Use additional sheets if necessary)

RECORD OF INVENTION

While most researchers keep notes and records to document their work and discoveries, they are often in a form that is not acceptable in a patent court as a valid "conception record" to prove when the INVENTION was first conceived. By completing both blocks of the following "Declaration of Witnesses", a conception record will be established. The date of witnessing gives VTIP a fallback position if earlier records and dates are not acceptable.

IMPORTANT NOTE: A WITNESS should be someone skilled in the art in which the invention is made, but who has not been a contributor to the work, e.g. a faculty member, a graduate student working in the field, etc.

DECLARATION OF WITNESSES for DISCLOSURE NO. 02.082

This INVENTION was first explained to me by the originators:

David Szakelyhidi, Joel Stitzel,

Alex Cardinolli

on the 12th day of September, 2001 and

understood by me, and/or the attached disclosure was read and understood by me on

the ______ day of ______________, 20____.

DATE REDACTED

ALFRED L WICKS

Printed Name Signature of Witness Date

This INVENTION was first explained to me by the originators:

David Szakelyhidi

DATE REDACTED

on the ______ day of ______________, 20____ and

understood by me, and/or the attached disclosure was read and understood by me on

the ______ day of ______________, 20____.

Printed Name Signature of Witness Date

ATTACHMENT A:
ACKNOWLEDGMENT OF UNIVERSITY OWNERSHIP

We, the undersigned, as the originators of Intellectual Property Disclosure No. 02.082 entitled:

do hereby acknowledge that VIRGINIA TECH (hereinafter referred to as the "UNIVERSITY"), is the owner of all rights, title and interest in and to the Intellectual Property, including any and all copyrights, patents, reissues and extensions thereof. The UNIVERSITY also is the owner of all rights, title and interest in any INVENTION even if such invention is not patentable.

We agree that we will execute all necessary assignments as requested by the UNIVERSITY, its successors and assigns, to facilitate the filing of patent applications and/or copyright registrations. We will render any assistance that is requested to aid in the preparation of such applications.

We understand that the UNIVERSITY may assign its rights, title and interest in and to the INTELLECTUAL PROPERTY.

Prior to the execution of this Acknowledgment, we have not granted the right or license to make, use, or sell said Intellectual Property to anyone except the UNIVERSITY, nor have we otherwise encumbered our rights, title, and interest in said Intellectual Property, nor will we execute any instrument in conflict with this Acknowledgment.

IN WITNESS WHEREOF, we have affixed our signatures:

Signature Date

Signature Date

Signature Date

Signature Date

DATES REDACTED

ATTACHMENT B:

ROYALTY SHARING FOR UNIVERSITY OWNED DISCLOSURES ASSIGNED TO VTIP, INC.

All royalties, rents, payments, or any cash receipts from the sale, assignment, transfer, licensing or use of the INVENTION shall be the property of the UNIVERSITY and VTIP and distributed according to provisions of the Intellectual Properties Policy current at the time of signature. VTIP, Inc. is authorized to apply an overhead rate of 12% on gross royalties to partially recover its costs of doing business. (VTIP's actual full cost recovery rate is about 49%). Please be aware that VTIP, Inc.'s sole source of funding is from those intellectual properties which generate royalty revenues. VTIP, Inc. does not receive any funds from the state of Virginia, VIRGINIA TECH, or the Va. Tech Foundation, Inc.

Policy 13,000 on Intellectual Property sets the royalty sharing among VTIP, the originators/creators/contributors and VIRGINIA TECH at 40%/50%/10% respectively. Below is an example of an Intellectual Property which generates royalty revenues, overhead, and direct expenses with one originator.

Intellectual Property # 2001
Gross Royalty Revenue $10,000
Less VTIP OH @ 12% ($ 1,200)
Less Legal Fees or other expenses of development ($ 3,500)
Balance to be distributed $ 5,300
VTIP - 40% $ 2,120
INVENTOR - 50% $ 2,650
Virginia Tech - 10% $ 530

We, the undersigned, as the contributors to (originators of) the Intellectual Property described in Intellectual Property Disclosure No. 02.082 mutually agree that any share of revenues to be paid to us shall be distributed as follows: (Percentages must total 100%. If all originators will share equally, indicate so by listing "equal" as the percentage, DO NOT LEAVE BLANK).

/ /		50 %
Date	Signature	Royalty Share
/ /		30 %
Date	Signature	Royalty Share
/ /	Joel D. Stitzel Jr.	20 %
Date	Signature	Royalty Share
Date	Signature	Royalty Share

DATES REDACTED

ATTACHMENT C:

NON-CONFIDENTIAL DESCRIPTION FOR MARKETING PURPOSES

Please provide a brief (approximately 250 words), non-confidential overview of the Intellectual Property that can be used to solicit interest from and inquiries for additional information by potential licensees. Also, excerpts from this description will be included in our annual catalog of technologies.

Each year, thousands of femoral and tibial internal fracture repairs are performed by orthopedic surgeons in the United States. Internal fixation of long bones using intramedullary nails (IMN) has decreased incidence of non-union, allowed shorter hospitalization time, and earlier weight bearing for the patient compared to other fixation methods. Orthopedic surgeons have expressed that one of the most difficult parts of this intramedullary nailing of long bones, is locating and drilling the interlocking screw holes. IMN interlocking requires the surgeon to locate the holes in the nail, center the drill, and advance the bit through the bone to meet them.

Many novel procedures and devices have been developed to assist the surgeon in distal locking of intramedullary nails, but have some disadvantages. These can include the need for extensive x-ray exposure, expensive x-ray equipment, high power consumption, active electronics in vivo, soft tissue damage, which all lead to inaccurate screw placement. For these reasons, a new prototype device for locating and drilling IMN distal interlocking holes has been developed. This prototype device uses magnetic sensors to locate a permanent magnet placed at a know distance from the IMN interlocking hole. A drill sleeve may be attached to the targeting sensors so that when they are aligned with the target magnet, the drill sleeve is aligned with the axis of the interlocking hole to be drilled. This new prototype device has significant advantages over existing devices, including the following. It has no active or passive electronics in vivo, no x-ray imaging is needed for targeting, while allowing real time feedback of alignment. It is a percutaneous technique, which can be adapted for use with existing IMN's. The new prototype also has low power requirements allowing battery operation, a single target magnet with unique axisymmetric field and novel magnet orientation, and adjustable sensitivity. Additionally, the new device allows visual, audible, or tactile positioning feedback. This prototype magnetic targeting device can improve orthopedic surgeons' ability to target and drill distal IMN interlocking screw holes. This device may allow shorter surgery, decreased x-ray exposure, and fewer complications for the surgeon and patient.

Attachment D

1. Introduction

Each year, approximately 14,000 femoral and 12,000 tibial internal fracture repairs are performed by orthopedic surgeons in the United States. Internal fixation of long bones has decreased incidence of non-union, allowed shorter hospitalization time, and earlier weight bearing for the patient compared to plaster cast or external fixation.[1,4] The procedure involves fixation of long bone fractures by insertion of a long, thin-walled, metallic nail into the medullary canal of the damaged bone. The surgeon introduces the implant by creating a hole in the proximal end of the bone that opens into the canal. The bone fragments are aligned and the device is passed through them, so as to create a means for internal support. The nail is prefabricated with holes in the proximal and distal ends, which are meant to accept interlocking screws. The addition of screws is essential to control rotation and translation of the bone fragments with respect to each other. It is necessary to align and drill through the bone to meet the proximal and distal interlocking screw holes of the nail. An x-ray image and actual picture of an IMN can be seen in Figure1.

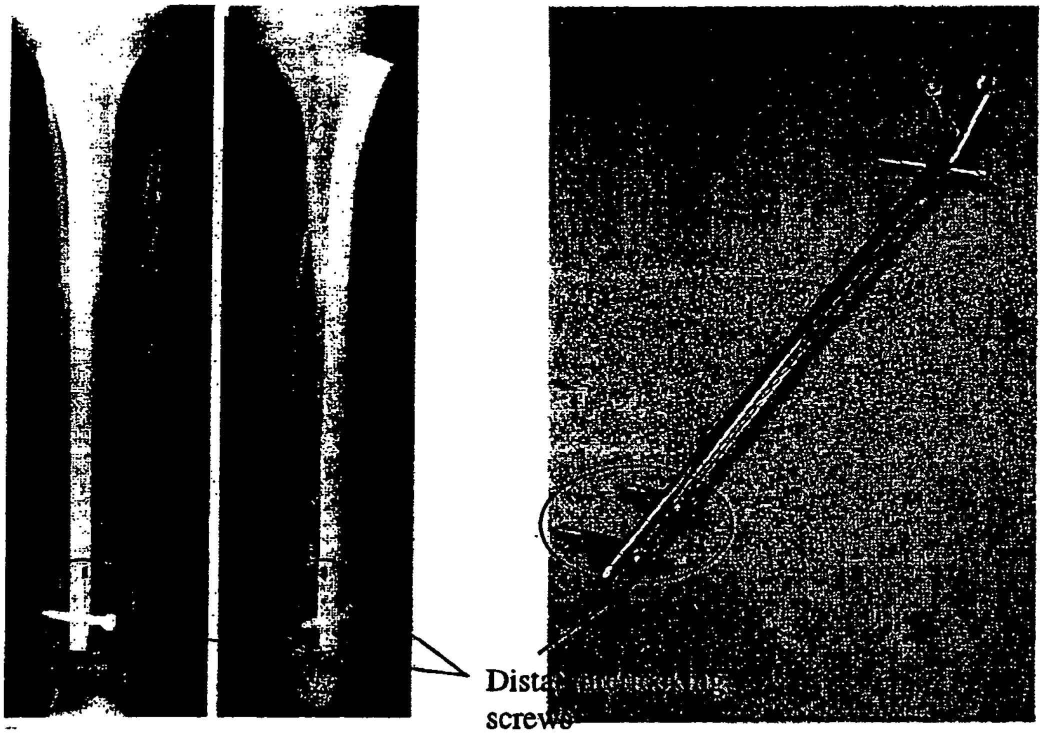

Figure 1) Intramedullary nail and fluoroscopic images of its insertion. The distal interlocking screws can be seen in the bottom of the x-rays.[4]

Since their introduction, all facets of the intramedullary nail (IMN) have evolved, from the shape and materials, to the methods and procedures used to implant them. While some procedures are generally agreed upon, orthopedic surgeons are in disagreement about many others. Discrepancies arise especially when looking at modern methods of interlocking screw insertion. In response, there is a great deal of work being done to improve methods for targeting, drilling, and inserting the distal interlocking screws. One important aspects of the IMN procedure is the placement of the interlocking screws. The performance of the surgeon and the device at this step can have a profound effect on the post-operative outcome. There is a wealth of literature available on the subject of intramedullary nailing of long bone fractures, but there is disagreement on which is the best device and procedure. One may be better suited for a certain fracture pattern than another. Improvements are needed for many of the devices. The first part of this research is to study current distal targeting techniques and find their advantages and disadvantages. From this review, a set of design requirements will be determined. Then, utilizing the design requirements, an alternative concept for interlocking screw hole targeting will be presented. The final efforts of this research will see the development of a prototype targeting device which can be applied to distal IMN interlocking screw hole locating and drilling.

2. Motivation

Orthopedic surgeons have suggested that one of the more difficult parts of intramedullary nailing of long bones, is locating and drilling the interlocking screw holes.[10] IMN interlocking requires the surgeon to locate the holes in the nail, center the drill, and advance the bit through the bone to meet them. The interlocking screws are then inserted. Proximal interlocking screw placement is relatively easy because the holes can be located with an external guide attached to the end of the IMN. However, it is found that this technique does not work well for distal interlocking.

Studies conducted have found large values of medial-lateral and anterior-posterior flexion of the distal nail after it has been inserted.[10,11,13] On insertion, the distal IMN exhibited mean lateral deflections of 4.5±3.5mm and dorsal deflections of 7.8±5.8mm. In addition, rotational deformations of the distal IMN have been measured at 0.3±0.7 degrees.[10] The orientation of coordinates is seen in Figure 2, where γ, β, and α indicate rotation about the x, y, and, z axis, respectively. The distal nail may deform from its original shape in any of these coordinates to some degree. The deformation of the nail is due to the shaping of the medullary canal where it is inserted. There are wide variations of the medullary canal shapes from person to person, and it is not currently possible to predict how the nail will deform accordingly. Therefore it is difficult to determine what the resultant location of the distal interlocking holes will be relative to their initial position.

There are tight tolerances between the screw and interlocking holes as seen in Figure 3. The angular deviation of the screw must be less than approximately eight degrees for no interference when inserted. Additionally, the lateral deviation should be less than 0.75 millimeter. To avoid any complications, it is important to place the interlocking screws accurately. These tolerances must be taken into account when targeting and drilling, so as to allow room for proper screw insertion.

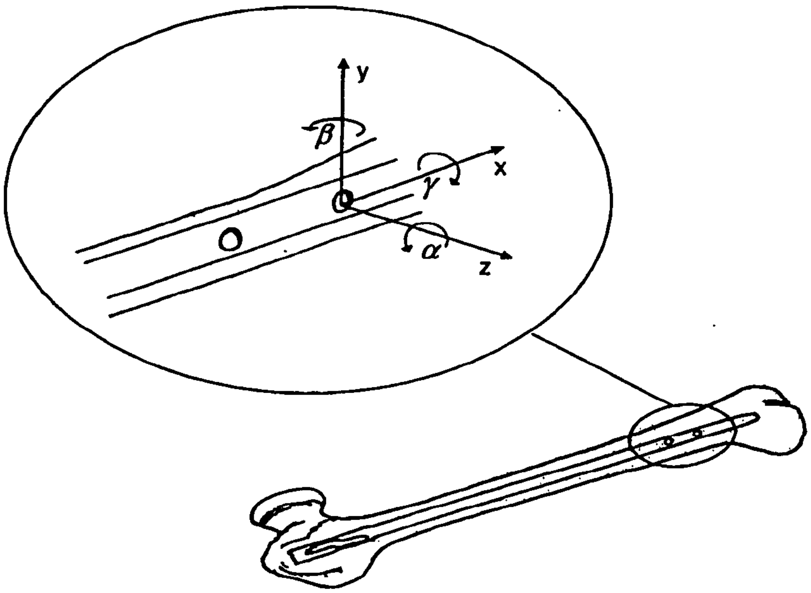

Figure 2) Coordinate system applied to the distal end of IMN, showing all possible degrees of deformation.

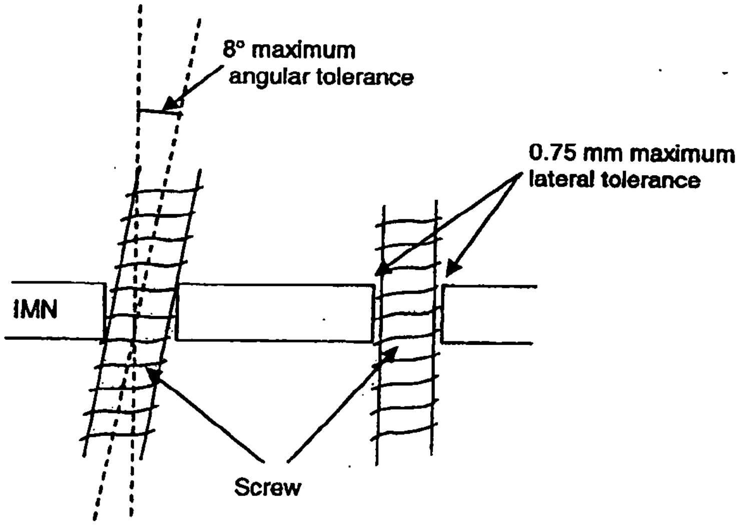
8° maximum angular tolerance
0.75 mm maximum lateral tolerance
IMN
Screw

Figure 3) Maximum tolerances for screw insertion angle and translation.

If the drill bit is not within the tolerance constraints or misses the hole, a second attempt must be made. Unfortunately, once a hole is started, it is difficult to correct. In some cases, the bone may be too weak to accommodate another hole, and then bone grafting or other means of fracture fixation must be employed. Repairing a missed interlocking can involve more damage to the patient's bone and soft tissue, while both the surgeon and patient must also endure additional x-ray radiation. It is reported that femur fracture malpractice, in which IMN's are often used, ranks first on the list of most frequent and third on the list of most expensive lawsuits against orthopedic surgeons.[2] For these reasons, many novel procedures and devices have been developed to assist the surgeon in distal locking of intramedullary nails correctly. These include mechanical guides, radiolucent targets, x-ray dependant devices, c-arm mount devices, and magnetic targeting. Each of these devices will be presented, along with the original freehand targeting technique, still preferred by many surgeons.

Initially, surgeons used the freehand technique. This technique requires the surgeon to align the tip of the drill bit at a point on the surface of the bone just above the interlocking hole, under x-ray imaging. Correct alignment is indicated when the desired interlocking hole appears as a perfect circle under fluoroscopy, with the drill bit in the exact center.[4] If alignment is lost, the drilling must be stopped and realigned using x-ray. The process of drill bit centering requires the soft tissue of the patient's extremity to be separated all the way to the bone so that the surgeon has sufficient room to maneuver. The desire to reduce damage of soft tissue during surgical procedures has led to the trend of percutaneous operating techniques. Percutaneous procedures are defined as inserting instruments and doing operations only through small skin incisions, reducing soft tissue damage. Overall, it has been realized that freehand alignment has many drawbacks such as excessive x-ray exposure, soft tissue damage, time consuming, and no real-time feedback of drill bit position.

Many aiming devices have been patented over the years. Some of these rely on the mechanical approach to distal hole location.[4,8,12,16] The simplest of these mechanical devices uses an external arm with holes that correspond to the hole locations in the IMN. Once the IMN is implanted, the external guide arm is attached firmly to its proximal end, creating a solid link. In theory, the distal targeting holes will then be aligned with the distal interlocking screw holes of the IMN, ultimately allowing a straight shot for the drill to penetrate the bone and holes.

Problems with externally mounted jigs arise because they don't account for IMN deformation. In response, attempts have been made to correct for the inaccuracies of current mechanical targeting. Several devices exist which have an external drill guide arm with an extra reference pin attached to correct for bending of the nail. These devices correct for nail flexion in the sagittal plane only and do not account for deformation in the frontal plane and axial rotation of the nail, which have been proven to be significant for misalignment in previous studies.[10,11] The device still requires x-ray for alignment of the reference pin, which also adds soft tissue trauma, an extra hole in the bone, and additional surgery time. These studies indicate that an externally mounted, mechanical aiming device of this kind is not adequate for targeting the distal holes.[10]

While some devices aim to eliminate use of x-ray imaging all together, others have attempted to minimize its use and maximize the efficiency. There are a multitude of devices in this category.[4,9,14,17,18,19] Generally, each employs some type of drill guide that is positioned under fluoroscopic imaging and then fixed in place when correctly aligned over the desired IMN interlocking hole. The dosage of radiation used with these devices is reduced compared to the amount used for freehand targeting. In addition, the surgical team is involved in many of these procedures each year from which their exposure compounds. The International Committee on Radiological Protection suggests limits on yearly occupational exposure.[6,15] It is recommended that medical procedures adhere to the concept of "As low as reasonably achievable" when dealing with this matter because even the smallest dosage can cause abnormal cell growth.[6] This statement is further support for development of distal targeting devices that are x-ray independent.

Additionally, x-ray devices must be employed in modern operating rooms equipped with c-arm fluoroscopy units and high powered computers. Consequently, they lose the advantage of portability and can not be used in primitive operating settings such as third world nations or temporary military hopsitals.

The desire to target accurately without fluoroscopic imaging has lead to the most recent attempts to use magnetic targeting. Devices have been developed that use external magnetic sensors to find the position of a flux field induced in the IMN by permanent or electromagnets. Some devices have even tried to magnetize the whole IMN and look for variations in the magnetic flux that occur around the interlocking holes.[20] Others devices target on a magnet placed inside the IMN at the same position as the hole.[3,5,7] The targeting device is usually attached to a drill sleeve to guide the bit for drilling.

Magnetic targeting has some significant advantages. Magnetic fields can penetrate the IMN and human tissue without being distorted or causing physiologic damage, unlike x-rays. Also, magnetic devices require little power, although some designs incorporate the use of computers to output positioning data. One notable drawback is that the majority of these targeting devices are manufactured to only work with specific nails, and are not adaptable to others. Additionally, devices that use electric current inside the body to create magnetic fields require stringent FDA approval because of their inherent danger. Although it is not yet perfected, magnetic distal targeting has shown the most promise, having the least drawbacks of all the x-ray independent techniques.

Design requirements for a targeting device should draw from the advantages of previous designs. The desired qualities describe a device with the following attributes.

- Requires minimal x-ray exposure for targeting, not including the dosage that may be required for final assessment of correct interlocking.
- Low power, so it can run on a battery for use in primitive settings, such as third world countries and battlefield operating facilities.
- Simple, so that the surgeon does not require extensive training to operate the device.
- Accurate and repeatable, so that the holes may be drilled inside the allowable tolerances and without requiring complicated set up or calibration procedures.
- Percutaneous, to keep soft tissue damage and the external appearance of scarring to a minimum.
- The device should be adaptable to most nail designs.
- Real time targeting, providing feedback of position while aligning and during drilling.

3. Approach

Using these design requirements, and building on what has been done successfully in the past, it is possible to develop a better distal interlocking screw targeting device and procedure. As mentioned, the magnetic targeting devices have shown great promise in providing optimal distal targeting independent of x-ray. Magnetic flux can penetrate human tissue and bone just as x-rays, but without the danger of radiation. In addition, the magnetic field sensors are used externally, so there is no soft tissue damage required for targeting, as in some other mechanical devices. Magnetic field sensors also have high resolution and are able to realize minute changes in their position within a field. For these reasons, magnetic field sensing has been adapted to the development of this IMN distal hole targeting design.

In order to align the drill bit with the axis of the desired interlocking hole, the surgeon must have feedback of positioning for rotation and translation in three dimensions. A coordinate axis was introduced in Figure 2, where it is assumed that the axis of the interlocking hole is z, and the x-y plane, normal to the face of the hole, is coplanar with the medial plane. This is the direction from which the surgeon will be locating and drilling the hole in the bone. The focus of this research is to use a permanent magnet and magnetic sensors to provide feedback for the surgeon to align the drill bit so that it is parallel to the axis of the hole for drilling.

This prototype targeting device will build on the existing magnetic distal screw insertion device developed by Dr. Durham.[5] The aforementioned device uses a magnet placed inside the IMN at a point in front of the distal screw hole to be targeted. The magnet is inserted on a rod through the proximal opening in the hollow nail, while its insertion depth is fixed by a locking pin. Once the magnet is in front of one of the distal holes, a skin incision is marked using a magnetic compass to locate the position of the internal magnet which projects central flux lines parallel to the axis of the hole. After the skin and tissue are separated to allow working room, another magnet on a central pivot inside a tube is inserted down to the bone surface. These two magnets attract each other and align a guide wire which is then inserted. The magnets are removed and a cannulated drill bit is advanced over the guide wire which is now aligned directly with the axis of the hole. Finally the interlocking screw is inserted and the procedure is repeated for the more proximal hole.

This new prototype uses the existing magnet insertion techniques, but applies an electronic approach to the targeting problem. The targeting device developed by this research is used to locate a permanent magnet that will be locked in place offset from the hole to be drilled. The north pole of the magnet must face medially (along the z-axis) so that it projects a magnetic field having a central line of flux parallel to the axis of the interlocking hole. From outside the extremity in which the IMN is inserted, the targeting will be performed by an array of magnetic sensors held parallel to the medial plane. Theses sensors will be embedded in a targeting device handle, which will have a drill sleeve attached at its distal end. Acceptable drill sleeves have been developed previously that could be retrofitted to this design. The distance between the center of the drill sleeve and the center of the magnetic sensor array will be equivalent to the distance between the magnet and hole inside the IMN. The sensor array is aligned correctly over the internal magnet, therefore the drill sleeve will be aligned with the hole to be drilled. The surgeon can advance the drill bit through without hitting the magnet, while maintaining alignment feedback in real time. The locking mechanism can be adapted from the previous design.[5] In the current design, a readout on the handle of the targeting device will have a "bullseye" of LED's which indicate position. The outside of the display will consist of a ring of red LED's, with one green LED in the center. The red LED's light to indicate which position the drill sleeve must move to have correct alignment. When aligned correctly, all red LED's will be off and the central green LED will be lit. The surgeon is then ready to drill the hole and insert the interlocking screws without aid of fluoroscopy or extraneous targeting systems. A schematic of the perceived device is presented in Figure 4.

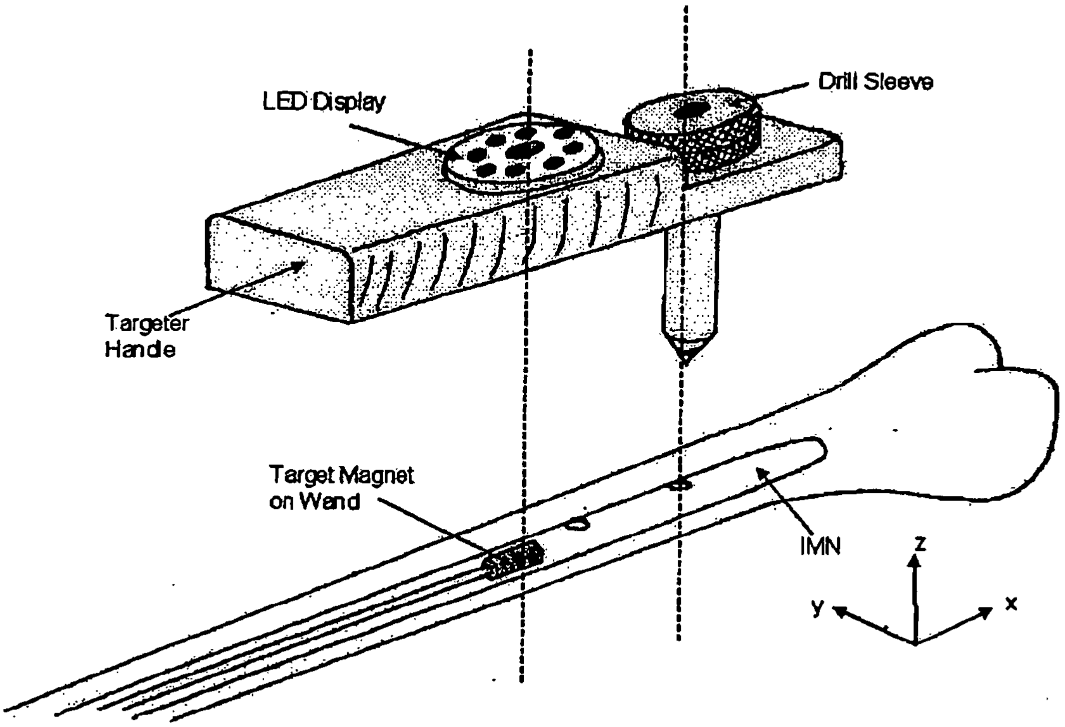

Figure 4) Perceived distal interlocking screw hole targeting device. The correct axis of alignment between the drill sleeve, hole, sensors, and target magnet are shown as the dotted lines.

4. Magnetic Field Targeting

To implement magnetic field targeting, issues including the target magnet, sensors, and electronics are considered. Different options are discussed for each issue. Computer modeling of the magnetic field will be shown. This will be compared to experimental results from mapping the voltage about the magnet with the chosen sensors. The functional sensor configuration for targeting is developed. The sensor array output is then used to provide visual feedback of drill bit position for the surgeon. The target magnet and sensor array are shown as adapted to the process of locating and aligning a surgical drill and its bit parallel with the interlocking screw holes of the IMN. Conclusions, recommendations for improvements, and alternative applications are presented.

a) Target Magnet Selection

In order to align and advance the drill accurately, the surgeon must know where the drill is in relation to the axis of the hole. This requires a target magnet that provides targeting information to resolve all degrees of freedom. Therefore, the magnetic field from inside the nail must have a shape and polarity that affords unique targeting information in all possible planes. For targeting with this approach, the flux lines have a peak and a non-circular field shape about the axis of each plane so that the targeting sensors may be aligned. A non-circular, axisymmetric field was selected, allowing the sensors to distinguish rotation about the z-axis, while the peak flux lines perpendicular from the magnet indicate its exact center.

In verification of this design, Ansoft's Maxwell 3D magnetic modeling program was used to compare various magnet shapes and orientations. The shape and polarity that was found to afford the optimal field, was a cylindrical Neodymium Iron Boron (NdFeB) magnet that is polarized across its axis. Figure 5 shows flux density above the magnet, as well as orientation of the magnet polarity. It can be seen that there is a definitive peak that remains parallel to the z-axis regardless of distance, which is important because the targeter and corresponding drill bit must remain parallel to the hole at all depths. The field from this magnet must be detectable at a maximum distance typically encountered between the center of the IMN and the outside of the patient's limb, which is approximately 10 centimeters. The peak of the field is detectable at this distance, also seen in Figure 5. For the small percentage of large patients whom have an IMN place in an extremity of exceptional diameter, the surrounding tissue can be compressed to bring the distance below 10 centimeters.

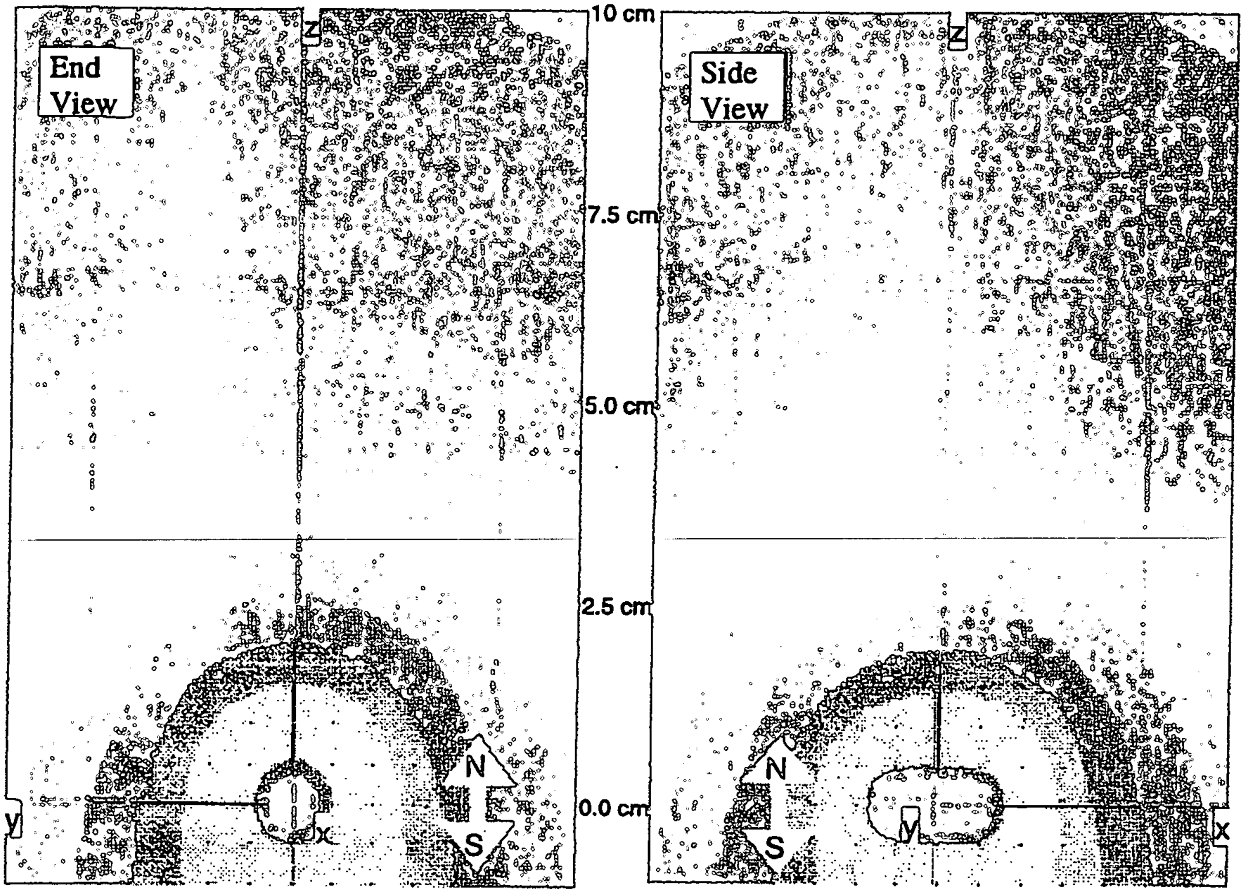

Figure 5) Plots of flux density in the y-z and x-z plane above the chosen cylindrical magnet. The peak is centered exactly over the magnet, parallel with the z-axis, and is detectable at the required targeting distance of 10 cm.

The prototype targeting device will be aligned in the medial (x-y) plane, requiring a magnetic field that has an axisymmetric shape to resolve rotation about the z-axis. This elliptic field shape can be seen in Figure 6. The elliptic shape of the field, in the x-y plane, allows feedback of rotation and translation about the magnet, which is placed next to the IMN interlocking hole.

An experimental validation of this modeling of the axisymmetric field shape in the x-y plane was performed. This was done by comparing the model's flus density plot of the x-y plane (Figure 6) to an actual mapping of the flux density recorded by a Gauss meter. The field of the magnet was mapped in 6mm steps over a 10cm by 10cm area. To further support the claim that the chosen magnet projects the desired field shape to the required distance, the flux density mapping was performed at +10cm in the z-direction. It can be seen in Figure 7, that the experimentally recorded field shape is very similar to the model.

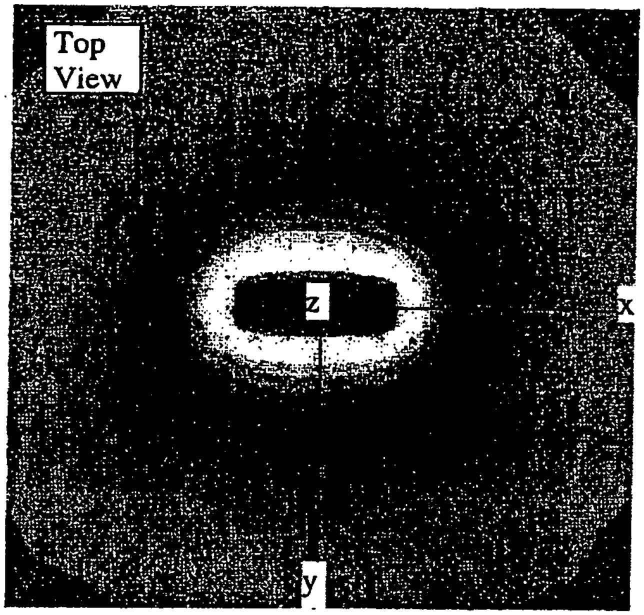

Figure 6) Plot of flux field around the magnct in the x-y plane. There exists a major and minor axis to the elliptic field, which can be differentiated by the targeting sensors to determine rotation about the z-axis. The north pole is facing in the positive z direction.

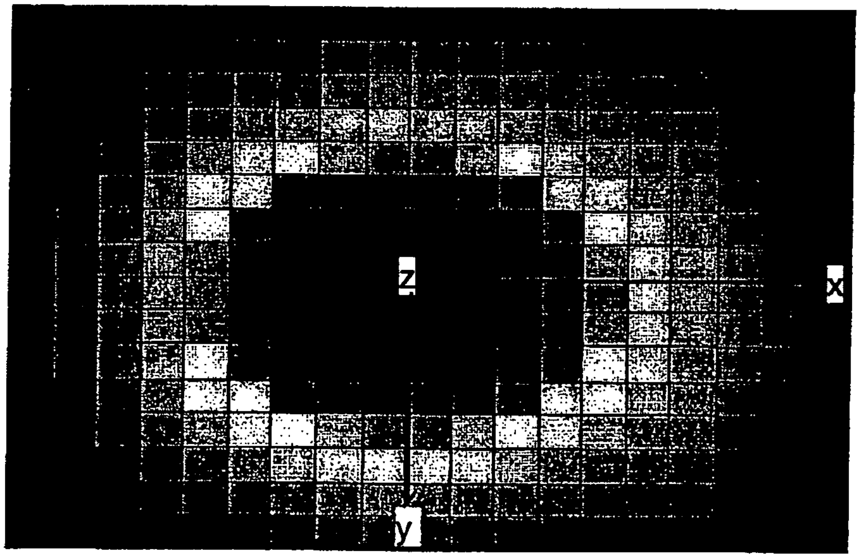

Figure 7) A portion of the mapping of flux density using a Gauss meter at 10cm above the target magnet in the +z-direction. Notice the axisymmetric field, as the model predicts in Figure 6.

Another important consideration is the physical properties of the magnet itself. A single, cylindrical NdFeB magnet proves to be a good selection. They are already approved by the FDA for internal use. Compared to other materials used for magnets, NdFeB has good temperature stability, can be formed in many shapes while being magnetized as desired, and has high magnetic energy per volume. It is also relatively inexpensive and easy to manufacture.

b) Targeting Sensors

Magnetic field sensing for this type of targeting requires the measurement of both magnitude and direction of flux lines in the field of the target magnet. The sensor should have sufficient sensitivity and resolution to operate at a range of 10cm from the target magnet. The field strength of the magnet at this distance will be below one Gauss, which is close to the value of Earth's magnetic field. Therefore, a sensor is needed that can sense very small changes in magnetic field. Sufficient resolution is gained by using a sensor that has a sensitive range of -2 to +2 Gauss. The field strength of the target magnet at the maximum 10cm distance falls into this range.

Magnetoresistive (MR) sensors, produced by Philips, closely match the requirements for this application. These sensors can provide sensing feedback for small variations of magnetic fields at a distance of 10cm from the target magnet. The sensitivity of the chosen sensors is 1.6 millivolts change per Gauss. The sensor readings can be nulled so that their outputs only represent changes in the flux lines emitted from the target magnet. This allows extraneous fields from other sources in the operating room to be ignored. Such extraneous sources could be the surgical drill, video monitors, lighting, and even the Earth's magnetic field.

The Philips MR sensors require only 120 milliwatts of power, which is appropriate for battery powered operation. The sensors can handle extreme environmental stress including high temperatures and chemicals. They can also be configured in an array, so that their collective outputs may be used for targeting.

c) Targeting Array

Each MR sensor produces a maximum output when flux lines are perpendicular to its sensitive side. This allows the angle and magnitude of the detected field to be known. In order to orient and align the targeting device in three dimensional space above the magnet, an elliptic array of sensors was developed. The array is configured so that the sensors are geometrically aligned with the flux lines of the target magnet. Each individual sensor is oriented perpendicular to the flux lines that project radially outward from the target magnet, while being centered about the peak flux lines emitted along the z-axis. A model of these flux lines in the x-y plane can be seen in Figure 7, along with the optimal placement of the sensors in the plane.

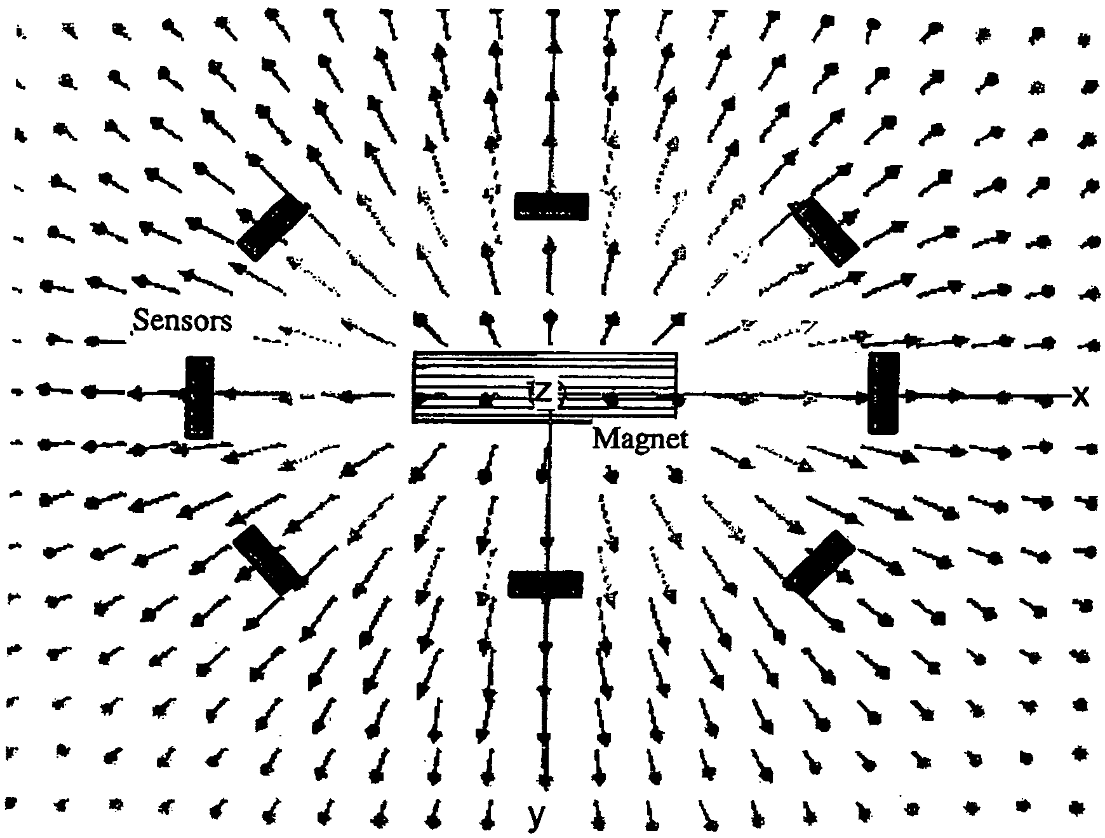

Figure 8) A Model of flux lines produced by the magnet. The elliptic array is shown, in which each sensor lies perpendicular to the flux field. This arrangement allows for equivalent voltage outputs from all the sensors when the array is centered in the flux field over the magnet.

This arrangement guarantees that each sensor in the array will be excited by the same magnitude and angle of flux when centered about the z-axis of the magnet, and will produce the exact same output voltage. The sensor array can move up and down in a plane perpendicular to the z-axis and retain the same feedback of position, because the field shape in that plane remains constant, it only becomes stronger as you get closer. When targeting, the voltage output of opposing sensors will be compared in order to determine their position and indicate which direction they need to be moved in the field relative to the peak.

d) Positioning Feedback

Using the sensor array output, continuous feedback is provided for the surgeon to center the drill above the interlocking hole in the medial plane. The positioning electronics are used to compare opposing sensor outputs and determine their location within the magnetic field, drive an LED display that visually indicates this position, and perform calibration of the sensors.

The sensors in the targeting array are sensitive to small changes in magnetic field, making it possible to determine position in the field with a resolution of less than a millimeter in translation and less than one degree of rotation. Calibration is necessary because each sensor has an inherent offset at zero field due to manufacturing tolerances. Additionally, it is necessary to null any extraneous fields present in the operating room. Circuitry is provided that zeros the output of each sensor so that the array is ready for targeting. Calibration must be done with the sensors held away from any strong magnetic field, including that of the target magnet, so that the reading is not biased.

Once calibrated, it is possible to use the array of sensors to provide positioning data. The array is an ellipse of eight sensors, arranged with four sensor pairs, each opposing one another. Recall that the elliptical sensor array is aligned exactly with the elliptical pattern of flux intensity around the center of the target magnet. Refer to Figure 7, showing optimal sensors placement in the magnetic field. With this in mind, it can be said that when the array is centered exactly over the target magnet in the medial plane, all sensors will have equal voltage outputs. Any deviation from exact center, in either rotation or translation, will cause an offset in opposing sensors pairs. By comparing voltage offset between opposing sensors in the array, it can be determined which direction in the field they must be moved to have equivalent outputs. A picture the sensor array board can be seen in Figure 9.

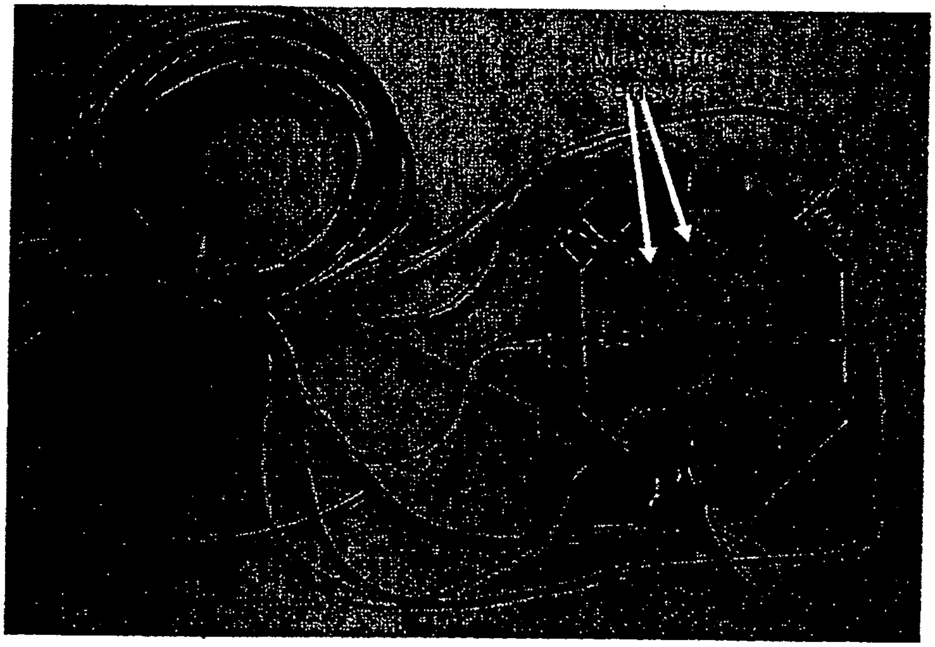

Figure 9) Arrangement of sensors fixed in a plastic housing to create an ellipse of opposing sensors pairs.

In order to convert these output voltages into a tangible indication of targeter position for the surgeon, a display must be created. The chosen display will be a "bullseye" of LED's, a ring of eight red lights around a central green light. Each LED will be tied to the corresponding sensor in the elliptic array. If a sensor pair has a voltage difference between them, it will be indicated on the LED display. An illuminated red LED means that the targeter must be moved in that direction to center itself. The position indicating LED's have a variable brightness that will decrease when the targeter is moving toward correct alignment. When all red LED's in the ring are off, the central green LED will light, indicating that the targeter is centered and ready for drilling. A picture of the LED display board can be seen in Figure 10. This visual feedback display can be mounted on a handle attached to a drill sleeve or even to the drill itself. Other feedback mechanisms could easily be incorporated if desired, such as tactile or audible indicators of position.

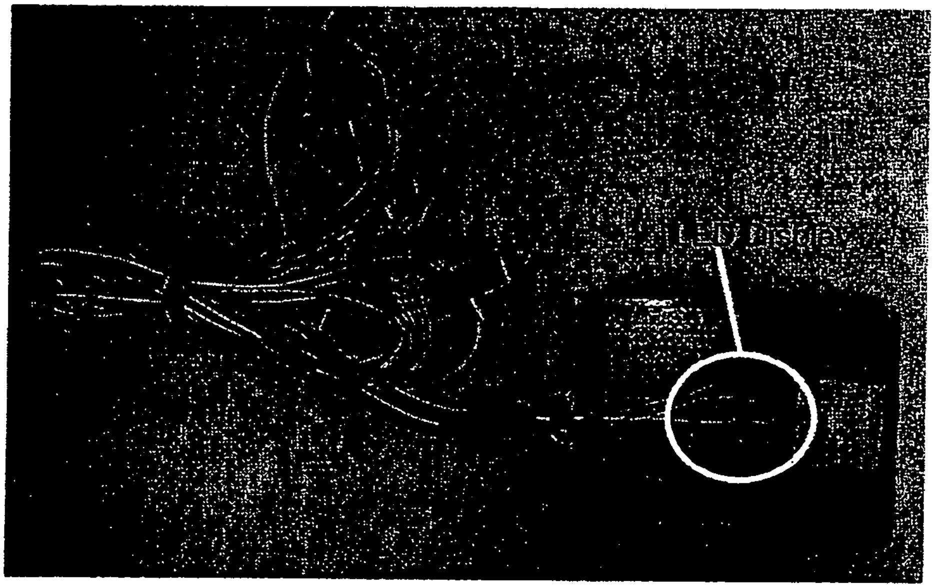

Figure 10) LED display arranged on the board in the form of a "bull's eye" for indicating correct alignment.

5. Prototype

A conceptual prototype which includes the target magnet, sensor array, visual display, and all necessary electronics has been developed. The prototype targeting device can be seen in Figure 11, without a handle or drill sleeve. Electronics are not shown. A schematic for the application of the prototype as a distal screw hole targeting device can be seen in Figure 4 and again in Figure 12, where a cut away of the embedded sensors are shown centered over the field of the target magnet. The prototype was developed and tested as a magnetic positioning device, able to locate itself relative to a target magnet.

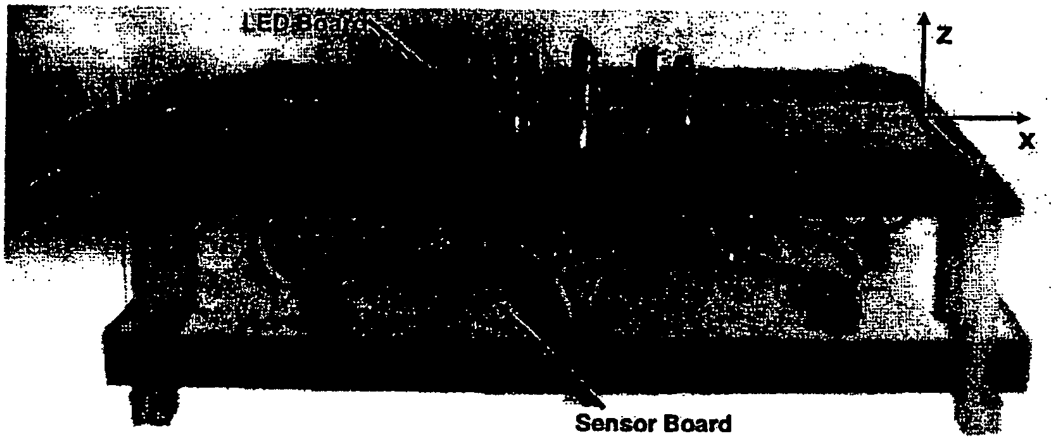

Figure 11) Prototype sensor array and LED display boards are shown connected and ready for targeting. The attached wires lead to the external positioning and calibration circuits.

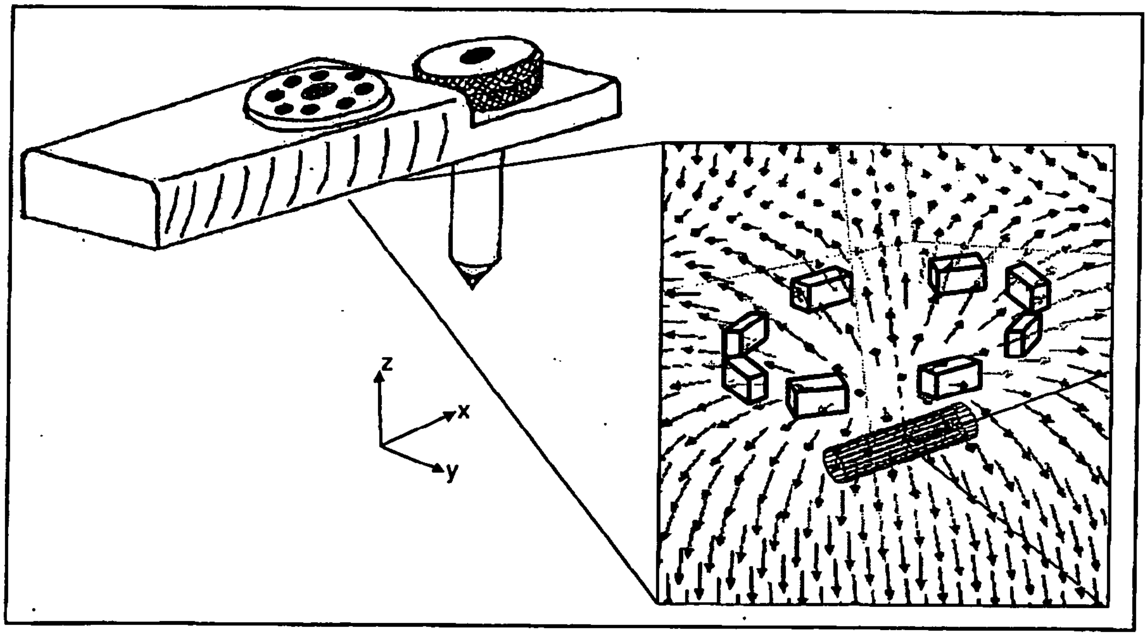

Figure 11) The sensors embedded in the handle are shown centered over the target magnet.

The prototype includes a calibration circuit used to zero the sensors prior to targeting. This allows any extraneous fields and individual sensor offsets present in the output to be canceled. A target magnet is then located by continuous feedback from the LED display. In the chosen configuration, the LED display will indicate if the sensor array is not flat in the medial plane or off center from the magnet. The ring of LED's will be off and the central green LED illuminated when alignment of the drill bit is achieved. When applied to IMN distal interlocking screw hole location, feedback of position is available for alignment and also during drilling. The LED display can even be used to make sure the screw is driven properly. Each successive interlocking screw hole may be fixed in this manner, working back proximally from the end, by pulling back the magnet to correct alignment with the next hole. A schematic of the targeter, showing the centering of the sensor array over the magnet can be seen in Figure 11.

This prototype device has the ability to distinguish rotational misalignment of about one degree, which is indicated by the appropriate LED's on the display. Sensitivity to rotational misalignment was determined by holding the prototype in a test fixture and rotating the target magnet below at a distance of 10cm. Translational misalignment sensitivity was determined by placing the prototype in a test fixture and moving it in the x-y plane at a distance of 10cm above the target magnet. An offset in the targeting plane of less than a millimeter from center caused indication of misalignment on the LED's. The sensitivity of this device is completely adjustable in the case that the user wants a different feel to the targeter. A change in the positioning electronics will allow almost infinite adjustment of sensitivity, which could be integrated as a variable switch. Reduction of sensitivity may also be required if targeting on an extremity where the sensor and magnet gap is smaller. An example in distal IMN screw hole targeting would be that the tissue surrounding the femur is much thicker than around the tibia, which affects the sensing distance and creates the need for adjustable sensitivity so that the electronics are not overloaded when the sensors are used in a stronger field.

6. Discussion

Orthopedic surgeons have expressed that one of the more difficult parts of IMN surgery, is locating and drilling the interlocking screw holes. Distal interlocking is a critical part of IMN surgery, and is also liable to present complications. The devices created to aid surgeons in distal hole targeting have been only marginally successful, while adding their own complications to the procedure. A new distal interlocking screw hole targeting device has been developed in accordance with the specified design requirements. This prototype device features an array of magnetic sensors, a target magnet, and necessary electronics for targeting and calibration.

This device is able to resolve all degrees of freedom needed to accurately align the drill bit with the central axis of the interlocking hole, within the given tolerances. This device gives feedback of position in real time, so that alignment can be maintained during drilling. The prototype device achieves targeting without x-ray exposure. Although fluoroscopy may be employed to check proper screw interlocking, this device has the potential to eliminate x-ray use during targeting.

The application of this prototype allows for a percutaneous approach to interlocking screw hole targeting and drilling. Also, it can be used to locate the exact location of skin incisions needed above the interlocking holes for insertion of the drill bit. A visual positioning display was created to provide feedback of drill alignment during targeting. It is also possible to provide configure the prototype to provide audible and tactile feedback as well. The prototype includes a calibration circuit used to zero the sensors prior to targeting. This calibration can negate the effects of extraneous magnetic field present in the operating room.

This device also has additional benefits. The prototype's target magnet could be adaptable to any nail, providing the nail is hollow and non-ferrous. The cylindrical magnet shape, with a diameter of less than 4mm, allows the magnet to be placed lengthwise in the smallest, hollow IMN's used for bones such as the humorous or tibia. The device has low power requirements and can be powered by battery. The prototype can be incorporated with existing drill sleeves, IMN's, and magnet insertion wands, while only needing a handle to be fabricated to connect all the pieces.

7. Conclusions

The prototype device developed has the potential to improve orthopedic surgeons' ability to target and drill distal IMN interlocking screw holes. The device functions as a precision magnetic targeter which orients a sensor array with the axis of a target magnet, providing feedback of alignment. Further development and testing is being performed to take this prototype to a functional stage for use in the operating environment. The electronics must be miniaturized, and a sterilizable housing and drill sleeve created for the final device. Phantom bone, cadaveric, and clinical studies must be performed to further the advancement of this device. It is anticipated that orthopedic surgeons would welcome such a device that could improve the success rate and healing time after IMN surgery by reducing operating room time, x-ray exposure, soft tissue trauma, and difficulty of interlocking.

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Attachment E

The original idea was developed equally by the originators in response to the presentation of a problem during a university class. All initial development during that class in the fall semester of [redacted] was performed without specific funding for that project. Work at that time was done in and outside of the university. During the spring semester of [redacted] work performed by any originators was also not funded. Work at that time was also done on and off university grounds. Funding was gained by Carilion Biomedical Institute during the summer of [redacted], in which originator, David Szakelyhidi, was compensated for work on the device until August of [redacted], when the funding ran out. That work was performed using university during regular hours. Originator, Alex Cardinalli, was funded for a two week period in [redacted] in which he worked on the project during regular university hours. The project was unfunded again from [redacted] of [redacted] until January [redacted]. During that unfunded period, work was performed on the project using university resources during and after university hours. The funding for originator, David Szakelyhidi, was renewed by Carilion Biomedical Institute in [redacted] of [redacted] That final funding cycle lasted until [redacted] which includes the development of the device in this disclosure to that date. During that funding period, work was performed using university resources and regular hours.

DATES
REDACTED